S. HRG. 98-310

IMITATION CONTROLLED SUBSTANCES ACT OF 1983

HEARING

BEFORE THE

SUBCOMMITTEE ON
ALCOHOLISM AND DRUG ABUSE

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-EIGHTH CONGRESS

FIRST SESSION

ON

S. 503

TO MAKE IT UNLAWFUL TO MANUFACTURE, DISTRIBUTE, OR POSSESS WITH INTENT TO DISTRIBUTE, A DRUG WHICH IS AN IMITATION OF A CONTROLLED SUBSTANCE ON A DRUG WHICH PURPORTS TO ACT LIKE A CONTROLLED SUBSTANCE

JULY 14, 1983

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IMITATION CONTROLLED SUBSTANCES ACT OF 1983

THURSDAY, JULY 14, 1983

U.S. SENATE,
SUBCOMMITTEE ON ALCOHOLISM AND DRUG ABUSE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:01 a.m., in room SD–628, Dirksen Senate Office Building, Senator Gordon Humphrey (chairman of the subcommittee) presiding.

Present: Senators Humphrey and Quayle.

OPENING STATEMENT OF SENATOR HUMPHREY

Senator HUMPHREY. Good morning. The subcommittee meets to hear testimony about the drug abuse problem that has defeated the best efforts of Federal and State law enforcement officials, the problem of look-alike drugs.

We have gathered a distinguished group of witnesses, both from the public and private sectors, who are doing their best with the law presently available to them to fight the sale of look-alike drugs.

I wish to thank those witnesses for coming, especially those who have traveled substantial distances at their own expense to share their knowledge and join in the search for solutions.

Look-alike drug manufacturers and distributors have been selling to our young people drugs that look like controlled substances but which actually contain only substances commonly sold over the counter, such drugs as diet aids, cold pills, and allergy remedies. In multiple doses, or with caffeine or aspirin, these substances produce a stimulant or a depressant effect like a controlled substance.

Tragically, when too many are taken, or they are combined with alcohol, there is a risk of severe hypertension, tachycardia, respiratory difficulty, cerebral hemorrhage, permanent brain damage, and even death.

The Food and Drug Administration has identified at least 12 deaths associated with the use of these drugs, and we will hear testimony this morning about one such needless death.

An additional danger is the risk that young people getting use to taking too many of these potent drugs may accidentally overdose on illegal drugs.

The imitation controlled substances are made with colors and markings similar to the illegal drugs they are mimicking, and often they are sold using street terms for amphetamines and barbi-

turates, such as "black beauties," "white crosses," "speed," and "yellow jackets."

Using a combination of magazine ads, mail promotions, flyers, and cards at entertainment events and in schoolyards, these drug dealers have successfully marketed look-alikes to college-age students, high school students, and sometimes even to children in elementary school.

The good news is that over 40 States have passed laws against look-alikes, many of them patterned after the Drug Enforcement Administration's model Imitation Controlled Substances Act.

The Postal Service has filed complaints under its false representation statute and obtained orders or consent agreements discontinuing mail delivery to these distributors. The FDA has seized materials and equipment from manufacturers who produce and mislable the counterfeit drugs, and has taken strong regulatory action against the triple combination most commonly used in look-alike drugs.

The bad news is that the response of the look-alikes industry has been simply to modify their production and marketing techniques so that these drugs are no longer looking like controlled substances, are properly labeled, and are not misrepresented in the advertisements. Manufacturers and distributors have moved to States where no look-alike laws exist or where there is a loophole in the State law which allows their business to flourish. They have stopped using the U.S. mails and have shifted to telephone orders, private carrier delivery, and credit card payment.

We are not talking about the legitimate over-the-counter drug industry which safely produces and markets the estimated three hundred products we depend upon for necessary self-medication.

The look-alike problem also has nothing to do with the generic drug industry. Our fight against look-alikes is aimed at those manufacturers and distributors who are marketing these legal substances to our young people to encourage recreational drug use. Our targets are those sellers who are making enormous profits in the sale and resale of these drugs with no regard for the health and safety of innocent bystanders.

Our concern is the fostering of a casual acceptance of drug use which undermines all of our drug prevention and treatment programs and may be the first step toward illegal drug use for some of the young people affected.

After careful review of the serious drug abuse problem, we became convinced of the need for new Federal legislation to solve the look-alike problem. In that regard, I have introduced two bills, S. 497 and S. 503, the latter of which, the Imitation Controlled Substances Act is now pending before this subcommittee. This act makes the manufacture and distribution and advertisement of look-alike drugs Federal crimes. The bill provides the FDA with clear jurisdiction over the look-alikes, and strengthens the FDA's current authority to enjoin distribution by manufacturers who have been found to be in the business of producing counterfeit drugs.

S. 497 amends the postal statute to make drug-abuse-oriented advertisements and shipments nonmailable.

The purpose of today's hearing is to discuss the nature and extent of the current use of look-alikes, the progress of State and Federal actions to ban look-alikes, development of community programs and school policies, and proposals for Federal legislation.

Let me put the rest of my statement in the record to save time.

[The remainder of Senator Humphrey's opening statement follows:]

We are fortunate to have with us representatives of the FDA, DEA, FTC, Postal Service, and the National Institute on Drug Abuse who will discuss the look-alike initiatives of their respective agencies. Several of the members of this Federal panel have earlier testified about the look-alike problem at House hearings before the Select Committee on Narcotics Abuse and Control and the Judiciary Committee's Subcommittee on Crime. We will welcome an update on the progress of their interagency cooperative efforts to solve the look-alike problem and their views on Federal legislation.

One of the most heartening aspects of the fight against look-alikes has been the rapid response of State legislatures to the look-alike problem. We will hear two different perspectives on that process this morning. One will be from the point of view of a State legislator, Representative Donna Sytek, who introduced a look-alikes bill that has just become law in New Hampshire. The second will be from Attorney General Baliles of Virginia who is still struggling against look-alikes, in spite of passage of State legislation last year.

Health professionals have become increasingly concerned about the threat of the health and safety of our youth by the increased use of these substances. In particular, the American Academy of Pediatrics has taken a lead in this area and developed a strong educational program. We welcome them here today and look forward to learning about their program.

Finally, and of critical importance, we shall hear from a panel of community leaders who are concerned and involved in the look-alike problem. They represent parents, teachers and local law enforcement officials who are on the front lines fighting against the invasion of look-alikes in to their communities. They are here appealing to us for help in that fight and we hope to broadcast that appeal to the American public today.

I look forward to learning from all of today's witnesses their perspective in this critical drug abuse problem and hope that out of today's hearing will come new ideas on how all of us, at the Federal, State, and local levels, can work together to solve the look-alike problem.

Senator HUMPHREY. At this point we will receive for the record a statement from Senator Hatch, chairman of the Committee on Labor and Human Resources, who is a cosponsor of the legislation.

[Senator Hatch's prepared statement follows:]

PREPARED STATEMENT OF SENATOR HATCH

Senator HATCH. It is my pleasure to participate in these hearings on imitation controlled substances. I share Senator Humphrey's sense of urgency in pursuit of an effective and appropriate regulatory conclusion. My friend and colleague, Senator Humphrey, deserves everyone's appreciation for his diligent effort in this most

important matter. I am pleased to cosponsor S. 503, which makes it unlawful to manufacture, distribute, or possess with the intent to distribute a drug which purports to act like a controlled substance.

This complex legislation is extremely important to protecting the health and promoting welfare of the American family. These imitation controlled substances in the form of pills have been found to be sold in community neighborhoods for the same intent and in the same fashion as illegal or prescription drugs. They contain combinations of substances commonly found in over-the-counter cold, allergy, and diet pills, which in multiple doses or in combination with caffeine produce stimulant or depressant effects similar to the controlled substances they are designed to resemble. Imitation controlled substances contain caffeine, ephedrine and phenylopropanolamine, ephedrine, lidocaine, or p,p'-diaminophenylmethane or even a mixture of other substances. Together or in high concentrations, they can become a lethal drug, especially when mixed with alcohol.

The manufacturers and distributors are actively promoting these pills as the "legal way to get high." Because none of the substances are classifed as "controlled substances", they can be purchased over the counter as candy or other nontoxic substances.

According to the Food and Drug Administration, there have been 12 deaths attributed to imitation controlled substances to date. Also, the sale of these pills has become a very lucrative and growing business, and is unfortunately following the trend of other nonlegal drugs in the street market. According to the Drug Enforcement Administration, mail order and storefront distributors grew from a mere handful in early 1980 to more than 150 outlets in November 1981.

We will learn today from Dr. Arthur Maron that he believes this Nation should be aware that adolescents and young adults are abusing medication. He states: ". . . Medication has until now been required as sufficiently benign to be available without prescription. Obtained through legitimate over-the-counter channels or through the purchase of "look-alikes" and used in place of controlled substances, this medication can cause problems. When these drugs are taken with other substances, such as alcohol, an even greater risk exists."

The American public wants the streets free of drugs. Mothers and Fathers want their children free from the temptations of illegal drugs. Now, we in America must stand up and demand that "over-the-counter highs" be discontinued.

I am pleased that this legislation carries the endorsement of the National Federation of Parents for Drug Free Youth, the American Medical Association, the American Association of Pediatrics and the National Youth Work Alliance. I hope that we, including the administration, can pull together to support passage of this legislation. If we are in any way endangering the life of our citizens, especially our Nation's youth, we must put a stop to it. I plead for unity on this very important issue.

Senator HUMPHREY. Our first panel is comprised of Mr. Joseph P. Hile, Associate Commissioner for Regulatory Affairs at the Food and Drug Administration; Mr. Gene Haislip, Deputy Assistant Administrator, Diversion Control of the Drug Enforcement Adminis-

tration; Ms. Amanda Pedersen, Deputy Director, Bureau of Consumer Protection, Federal Trade Commission; Dr. James Cooper, Assistant Director for Medical Affairs, National Institute on Drug Abuse; Mr. Charles P. Nelson, Assistant Chief Postal Inspector for Criminal Investigations, U.S. Postal Service.

Good morning to all of you. Thank you for coming, and we will begin in the order listed with Mr. Hile.

I say this to all witnesses: We will include your statements in full, and because of the large number of witnesses we have—11—I would encourage you to summarize your testimony so as to save time for questioning.

Mr. Hile.

STATEMENT OF JOSEPH P. HILE, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; GENE R. HAISLIP, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE; AMANDA B. PEDERSEN, DEPUTY DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION; JAMES R. COOPER, ASSISTANT DIRECTOR FOR MEDICAL AFFAIRS, NATIONAL INSTITUTE ON DRUG ABUSE, ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION, U.S. PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND CHARLES P. NELSON, ASSISTANT CHIEF POSTAL INSPECTOR FOR CRIMINAL INVESTIGATIONS, U.S. POSTAL SERVICE, A PANEL

Mr. HILE. Thank you very much, Mr. Chairman. As you so well summarized in your opening statement, look-alike drugs contain ingredients that may be purchased without prescription, and for the most part are common to a large number of legitimate over-the-counter remedies, such as decongestants, sleep aids, weight-reduction aids, and stay-awake aids.

Originally, look-alike drugs were manufactured to mimic the appearance and markings of various prescription-controlled substance products, such as amphetamines, Quaaludes, and similar drugs with abuse potential.

Today, however, what we still call look-alike drugs often tend to adopt fanciful shapes and colors of their own, and even have been found to bear the manufacturer's own copyrighted logo.

There is evidence, however, that leads us to presume that they still are ultimately sold to consumers as being controlled substances.

The manufacturers of these products adopt all the trappings of legitimacy by registering with us and complying with our good manufacturing regulations and labeling requirements. Distributors advertise with terms and phrases that are similar to those used to promote legitimate over-the-counter caffeine stay-awake products. In many respects, the problems for law enforcement purposes has become one of hidden intent to market a drug for abuse in the guise of a legitimate over-the-counter product.

When the industry began to shift away from products that resembled controlled substances in appearance, the agency brought action against products containing the triple combination of caffeine, phenylpropanolamine, and ephedrine, on grounds that they were unapproved new drugs which could not be shipped in interstate commerce. Implementation of this policy resulted in the destruction of nearly 23 million dosage units.

The industry reacted by evolving, this time by dropping one or more ingredients in order to evade our new drug authority. But we now are considering whether this authority could be used against such products. If we can prove that we can reasonably apply our new drug authority to emerging forms of look-alike products, we will certainly do so.

The look-alike drug-abuse phenomenon is unique because it takes advantage of the well-accepted principle of health care that people can and ought to be able to administer their own medication whenever feasible. The self-medication concept has generated a multibillion-dollar industry in this country which produces an endless array of useful products for a host of ailments. The ingredients used by the look-alike manufacturers are legitimately found in many of them.

The safety and efficacy of the overwhelming majority of commonly used products for self-medication is being reaffirmed by the over-the-counter drug review program of the Food and Drug Administration. Panels of experts involved in the OTC review have already recommended to FDA that the active ingredients in many look-alike drugs are safe and effective individually and in various combinations for many indications for over-the-counter sale.

The enormous number of products containing these ingredients that are sold in drug stores, grocery stores, convenience stores, newsstands, airports, and literally everywhere to people like you and me every day presents the legislator as well as the regulator with an extraordinary problem. Unless the manufacture and/or distribution of legitimate over-the-counter drugs is to be modified in some manner for the purpose of isolating the look-alike forms of these products, a way to distinguish them must be crafted which would enable law enforcement officials to know whether the capsules or tablets they are holding are or are not look-alikes.

One approach, of course, would link the status of a particular capsule or tablet to the intent which we believe must exist to manufacture and distribute a drug of abuse. This intent might manifest itself circumstantially above the street level through the chain of manufacture and distribution, but we doubt whether it would reveal itself either directly or sufficiently without an investigation, probably undercover in nature, up through that chain of distribution. An investigation of this type would require the expertise of an agency primarily responsible for traditional criminal law enforcement.

The frustration of experiencing only a partial success against the look-alike industry, however, has led us to examine the sufficiency of existing as well as proposed legislation. In this regard, we also have sought to develop a better understanding of how Federal and State authorities and resources could best complement one another.

I am convinced that a strong State commitment is just as essential as the assumption of leadership responsibility by the Federal Government. Many actions might most effectively be taken locally—for example, criminal investigations which need to begin at the street or storefront levels in order to establish a chain of illegal intent. I am aware that this view is complicated by a lack of uniformity among State laws and differences in priorities and resources. To the extent that the Federal Government can mitigate these complications through model legislation, exchanges of information, and other technical assistance, it should do so.

From our standpoint, the Food and Drug Administration remains committed to enforcement activities against look-alikes whenever possible within its investigational capabilities. If we can craft new legislation which would facilitate our efforts, we will.

In all candor, however, legislation which would require infiltration, or obtaining evidence of street sales or engaging in related undercover activities for the purpose of establishing a criminal intent to promote a product for purposes of drug abuse should not be imposed on FDA, because its investigators are neither hired nor trained for this kind of activity. Men and women who joined the agency to serve the public through such activities as factory inspections should not be asked to undertake, without police training and without police weapons, the risks associated with the type of undercover investigations that would be necessary to enforce effectively a statutory provision of that type.

Lately, as we have gained greater experience in regulating look-alikes, the Food and Drug Administration has been considering whether it should propose that the Department of Health and Human Services seek additional authority. One possible change would enable our investigators to review the manufacturing and distribution records of firms which are or appear to be in the OTC look-alike business. Presently, FDA investigators can inspect these firms, but have always lacked access to records when prescription drugs are not involved. A narrow exemption from this prohibition, possibly on an ingredient basis, could provide valuable information which we could use immediately if the products involved were illegal under our authorities, or which we could provide to criminal law enforcement agencies for their use.

Such information could prove extremely helpful, for example, to State officials who need to know distribution schemes within their areas of jurisdiction. It could also provide evidence which might be useful in an investigation of manufacturers who, by operating on a contract basis with distributors that place orders with them, can generally hide any direct evidence that they intend their products to be used for drug abuse.

Another area, Mr. Chairman, which you have recognized is of particular interest, has involved an expansion of FDA's injunction authority to cover the counterfeiting of drugs. Presently, FDA can obtain seizures against counterfeit drugs and equipment used to make them, but these are directed only at the specific items which are seized and do not cover any replaced drugs. An injunction, in contrast, would prohibit a manufacturer or distributor from continuing the same activities.

Mr. Chairman, we feel at FDA that our accomplishments against the look-alike drug industry have been very positive and we intend to continue our efforts and expand them wherever we can. But the Food and Drug Administration is not and should not become a traditional criminal law enforcement agency. Our primary mission is elsewhere. If the war against look-alike drugs is to be successful, other entities will have to complement our efforts by assuming greater responsibilities in the areas of their expertise.

Mr. Chairman, that concludes my statement.

[The prepared statement of Mr. Hile follows:]

STATEMENT

BY

JOSEPH P. HILE

ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman:

I am pleased to have this opportunity today to update the Subcommittee on the status of the look-alike drug problem from the perspective of the Food and Drug Administration.

As you are aware, FDA has initiated a number of actions over the last several years to disrupt the manufacture and distribution of look-alike drugs. In many respects, the form that the industry assumes today reflects its responses to our efforts to control it. Originally, we expected that our seizures of look-alike drugs in September 1981 would resolve the problem by having a substantial deterrent effect. But the industry has evolved and, by necessity, our thinking has had to evolve with it. This is an appropriate moment, therefore, to share our experiences and views with you.

THE INDUSTRY EVOLVES

As we all know, look-alike drugs contain ingredients which may be purchased without a prescription and, for the most part, are common to a large number of legitimate over-the-counter (OTC) remedies, such as decongestants, sleep aides, weight reduction aids and stay awake aids. Originally, look-alike drugs were manufactured to mimic the appearance and markings of various prescription controlled substance products such as amphetamines, Quaaludes and similar drugs with abuse potential. This resemblance enabled us to base our first seizures on the prohibition in the Federal Food, Drug, and Cosmetic Act against the counterfeiting of drugs.

Manufacturers and distributors soon recognized that FDA's "counterfeit" authority could be ineffective against products which no longer closely resembled the appearance of controlled substances. As a result, the term "look-alike" became something of a misnomer as firms successfully transformed these products into drugs that no longer closely resembled controlled substances. Today, what we still call "look-alike" drugs often tend to adopt fanciful shapes and colors, and even have been found to bear the manufacturer's own logo. Presumably, they still are ultimately sold to consumers as being controlled subtances.

The manufacturers of these products adopt all the trappings of legitimacy by registeing with use and complying with our good manufacturing regulations and labeling requirements. Distributors advertise with terms and phrases that are similar to those used to promote legitimate, over-the-counter caffeine stay awake products. In many respects, the problems for law enforcement purposes has become one of hidden intent to market a drug for abuse in the guise of a legitimate over-the-counter product.

FDA'S NEW DRUG AUTHORITY

By contrast, FDA's successes so far have involved products which could be seized without regard for the intent of the manufacturer or distributor. When the industry shifted away from products that resembled controlled substances in appearance, FDA could still conclude that the predominate combination of OTC ingredients in these

products, the so-called "triple combination" of caffeine, phenylpropanolamine (widely used as an appetite suppressant and nasal decongestant), and ephedrine (a decongestant) was outside the scope of the Agency's ongoing Over-the-Counter Drug Review Program -- a ten year effort to determine the safety and efficacy of more than 700 active ingredients in some 300,000 OTC products -- on the grounds that it had never appeared in any legitimate products. The Agency brought action against products containing this triple combination on the grounds that they were unapproved new drugs which could not be shipped in interstate commerce. Implementation of this policy resulted in the destruction of nearly 23 million dosage units.

The industry reacted by evolving again -- this time by dropping one or more ingredients in order to evade our new drug authority. We now are considering whether this authority, or our authority over "imitation" drugs, could be used against such products. However, the application of the new drug authority to products containing fewer than the three-ingredient combination raises difficult problems for us since the combinations involved tend to appear in legitimate over-the-counter products. As the OTC Drug Review Program was orginally conceived, such combinations would be exempt from regulation as unapproved new drugs until completion of the review.

We continue to believe in the fundamental wisdom of this policy since it helps preserve the continuity and integrity of the OTC Drug Review. But if we conclude that we can reasonably apply our new drug authority to emerging forms of look-alike products we will do so.

LEGISLATIVE STRATEGIES: SOME GENERAL CONSIDERATIONS

The look-alike drug abuse phenomenon is unique because it takes advantage of the well-accepted principle of health care that people can and ought to be able to administer their own medication whenever feasible. The self-medication concept has generated a multi-billion dollar industry in this country which produces an endless array of products for a host of ailments. The ingredients used by the look-alike manufacturers are legitimately found in many of them.

The safety and efficacy of the overwhelming majority of these products for self-medication is being reaffirmed by the Over-the-Counter Drug Review program. Panels of experts involved in the OTC Review have already recommended to FDA that the active ingredients in many look-alike drugs are safe and effective individually and in various combinations for many indications for over-the-counter sale.

The enormous number of products containing these ingredients that are sold in drug stores, grocery stores, convenience stores, newsstands, airports--literally everywhere--to people like you and me every day, presents the legislator (as well as the regulator) with an extraordinary complication. Unless the manufacture and/or distribution of legitimate over-the-counter drugs is to be modified in some manner for the purpose of isolating the look-alike forms of these products, a way to distinguish them must be crafted which would enable law enforcement officials to know whether the capsules they are holding are, or are not, look-alikes.

One approach, of course, would link the status of a particular capsule (look-alike vs. legitimate) to the intent which we believe must exist to manufacture and distribute a drug of abuse. This intent might manifest itself circumstantially above the "street" level through the chain of manufacture and distribution, but we doubt whether it would reveal itself either directly or sufficiently without an investigation--probably undercover in nature--up through the chain. An investigation of this type would require the expertise of an agency primarily responsible for traditional criminal law enforcement. The Food and Drug Administration is not that type of law enforcement agency.

LEGISLATIVE STRATEGIES: SOME SPECIFIC CONSIDERATIONS

The frustration of experiencing only partial successes against the look-alike industry has led us to examine the sufficiency of existing as well as proposed legislation. In this regard, we also have sought to develop a better understanding of how Federal and State authorities and resources could best complement one another.

Last month, we sponsored a conference on look-alike drugs, along with the Drug Enforcement Administration and the U.S. Postal Service, with Attorneys General and other State officials from around the country for the purpose of sharing experiences and obtaining advice. I can certainly say that we heard a wide range of views which resulted in a lively and thought provoking discussion.

I came away from the conference convinced that a strong State commitment is just as essential as the assumption of leadership responsibility by the Federal government. Many actions might be most

effectively taken locally; for example, criminal investigations which need to begin at the "street" or "storefront" levels in order to establish a chain of illegal intent. I am aware that this view is complicated by a lack of uniformity among State laws and differences in priorities and resources. To the extent that the Federal government can mitigate these complications through model legislation, exchanges of information, and other technical assistance, it should do so.

From our standpoint, the Food and Drug Administration remains committed to enforcement activities against look-alikes whenever possible within its investigational capabilities. If we can craft new legislation which will facilitate our efforts, we will.

In all candor, though, legislation which would require infiltration, or obtaining evidence of "street" sales or engaging in related undercover activities for the purpose of establishing a criminal intent to promote a product for purposes of drug abuse should not be imposed on FDA because its investigators are neither hired nor trained for this kind of activity. Men and women who joined the Agency to serve the public through such activities as factory inspections should not be asked to undertake, without police training and without police weapons, the risks associated with the type of undercover investigations that would be necessary to enforce effectively a statutory provision of that type.

For a period in our history, FDA did exercise authority over illegal trafficking in certain classes of abused drugs, and in the mid-1960's established a Bureau of Drug Abuse Control to administer the then newly-enacted Drug Abuse Control Amendments to the Federal Food, Drug, and Cosmetic Act. These amendments authorized FDA to seize illegal drug supplies, serve warrants and arrest violators. However, the new bureau was later merged with the Bureau of Narcotics of the Treasury Department to become the Drug Enforcement Administration in the Department of Justice--a reasonable and logical combination of like functions.

Lately, however, as we have gained greater experience in regulating "look-alikes", the Food and Drug Administration has been considering whether it should propose that the Department of Health and Human Services seek additional authority. One possible change would enable our investigators to review the manufacturing and distribution records of firms which are or appear to be in the OTC look-alike business. Presently, FDA investigators can inspect these firms, but have always lacked access to records when prescription drugs are not involved. A narrow exemption from this prohibition -- possibly on an ingredient basis -- could provide valuable information which we could use immediately if the products involved were illegal under our authorities, or which we could provide to criminal law enforcement agencies for their use.

Such information could prove extremely helpful, for example, to State officials who need to know distribution schemes within their areas of jurisdiction. It could also provide evidence which might be useful in an investigation of manufacturers who, by operating on a

contract basis with distributors that place orders with them, can generally hide any direct evidence that they intend their products to be used for drug abuse.

Another area of interest has involved an expansion of FDA's injunction authority to cover the counterfeiting of drugs. Presently, FDA can obtain seizures against counterfeit drugs and equipment used to make them, but these are directed only at the specific items which are seized and do not cover any replaced drugs. An injunction, in contrast, would prohibit a manufacturer or distributor from continuing the same activities.

SUMMARY

We at FDA feel that our accomplishments against the look-alike drug industry have been very positive and we intend to continue our efforts and expand them wherever we can. But the Food and Drug Administration is not and should not become a traditional criminal law enforcement agency. Our primary mission is elsewhere. If the war against look-alike drugs is to be successful, other entities will have to complement our efforts by assuming greater responsibilities in the areas of their expertise. Mr. Chairman, this concludes my formal statement. I will be happy to answer any questions you may have.

Senator HUMPHREY. Thank you very much. Mr. Haislip?

Mr. HAISLIP. Mr. Chairman, thank you for this opportunity to appear on an important problem that has concerned the Drug Enforcement Administration for some time. It is a problem that concerns drugs, but not the kind of drugs that are controlled by the Drug Enforcement Administration. In spite of that, it certainly impacts very heavily on the Nation's drug abuse problem in a number of ways.

The manufacture and distribution of the so-called look-alike drugs represents an effort to profiteer and exploit the Nation's drug problem by seeking out the loopholes that exist in our various State and Federal laws. And I think that, as you have yourself summarized, this produces injury, and, in addition to that, it encourages drug abuse, particularly among a great many young people who are oftentimes the target of this kind of activity.

So that at DEA, even though this was not a matter within our jurisdiction, we recognized that it was an important national matter, and that we had a responsibility to participate in possible solutions to it.

What I would like to do is very briefly summarize the development of the problem and our responses to it and the changes which have come about, because, we are hopeful that perhaps this would indicate the direction we should go in further administrative or legislative approaches to it.

Well, the look-alike problem, as we call it, that is, the manufacture and distribution of drug products that look like controlled drugs, is not such a new phenomenon. It began a number of years ago, but it was only recently, approximately 1979 and 1980, that it suddenly became explosive and widespread affecting a great many citizens in virtually every State of the Union. At that time it was clear to us that it would be necessary for the Federal Government to take a leadership role in responding to it. We have done that in a number of ways.

First of all, I should note that the Postal Service had already begun important investigations impacting on this problem in terms of the misuse of the mails in dealing with the look-alike problem. DEA organized an interdepartmental group consisting of the agencies that would have the most interest and authority to deal with the problem and, since that time, we have met and coordinated the activities in which we were each separately engaged. The Food and Drug Administration, as has been described, has taken an extremely active role within the limits of its present authority to attack the problem.

At DEA, we have designed a model State look-alike law which we recommended through our contacts with State enforcement agencies, State legislatures, the professions, and through the industry, and we are pleased that some form of that law has been enacted in 41 States and is pending in 8 others. I think that this is an enormous accomplishment, within a short period of time, and shows the seriousness and responsibility with which State officials have viewed this problem.

In addition, we sought voluntary cooperation from sectors of the industry that have been equally appalled to see this development. We contacted the Nation's principal capsule manufacturers and

asked them to investigate some of their sales and impose voluntary restraints, and they did that with admirable effect. At the time that we did this, capsules were the dominant product. We will see in a moment, if I can show you a little information we have collected, that that is no longer the case because of the voluntary responses of our industry.

Well, these steps have been effective. They have been effective in curbing what we called the look-alike problem. The look-alike problem, it seems, is about to disappear. But, it has been replaced to some degree with a newer problem and one that poses a good deal more difficulties. This is what we sometimes call the non-look-alike look-alikes, or what we might call the act-alikes, because, although they no longer look like controlled drugs, the suggestion in the advertisement is that they act like controlled drugs. And this is the new problem that we are seeing.

I would like to just very briefly show you the information that I have here and tell you what it does indicate.

From this chart here you can see that the problem escalates through 1980, which is when we begin to take our aggressive measures at the Federal level.

Senator HUMPHREY. What does that measure?

Mr. HAISLIP. These are the data representing exhibits that were submitted to the DEA laboratories from DEA investigation, also by State and local enforcement officers who were encountering these preparations in the illicit traffic. This is what this data represents. Of course, as with any body of data, there are serious questions and problems with it. But you will see that the pattern is quite clear here.

Well, beginning in 1980, the Food and Drug Administration, the Postal Service, and DEA began the measures that they could take within existing authority. The result seems to be, based on the data we have through our laboratory, that there is a precipitous decline in the availability of look-alike products. That doesn't necessarily speak to this newer problem. This is based on the number of exhibits submitted to us, and this is based on the total number of pills or capsules submitted to us. The charts are about the same.

The second chart deals with the problem of capsules and tablets. You will recall earlier the look-alike problem was primarily one involving capsules and at that time we did ask the capsule manufacturers to undertake voluntary measures, which they did. We can see that this has been effective, though a problem remains.

This last chart—again, this is all based on our laboratory data, which does have its limitations—but in the last chart each line represents the kind of drugs in these various compounds.

Now, the important line here is the red line which was the so-called triple-entity product, those look-alikes that contained the three drugs we are most concerned with. We believe that this shows that when the Food and Drug Administration took its action against the triple-entity product there was, as we would expect, a very sharp decline in that particular aspect of the problem.

This blue line represents the double-entity products and that line is up. This is in part——

Senator HUMPHREY. Let me interrupt you there, and ask how was this triple entity established and do you have the authority to do that for a double entity?

Mr. HAISLIP. This is a question that the Food and Drug Administration would have to respond to, and I would be glad to yield to my colleague for that.

Senator HUMPHREY. All right, Mr. Hile.

Mr. HILE. Several things are taken into consideration, Mr. Chairman, whether a product is a new drug or not a new drug, whether it has been demonstrated to be safe and effective is the principal focus of our attention. And that demonstration can come about either through the development of newly established evidence as a consequence of carrying out studies that are presented to us or as a consequence of long-marketed use and large numbers of study results published in the open literature.

We are also concerned over the reasonableness of the combination of drugs.

Senator HUMPHREY. OK; let me come back to that, I don't want to interrupt.

Mr. HAISLIP. If I may conclude this, what we see is that the look-alikes problem seems to be rapidly being extinguished, I think due to the efforts that we have undertaken and the efforts that the States have undertaken, but we have a different problem with—I believe at least at this time is of smaller dimension, but is clearly growing—which concerns the marketing of preparations like this which do not look like controlled drugs, but which contain the same product that these earlier look-alikes contained.

Now, you have here a typical advertisement that appeared in what I would describe as a drug-oriented publication, such as the High Times. If you are not familiar with it, it is the publication that has a number of articles on how to cultivate your own marihuana and various drug-oriented subjects of that kind. This advertisement is being found in this particular magazine; it is probably one of 30 or 40 such advertisements that are here.

And the important thing about it is that it is not improperly labeled nor does it appear to look like a controlled drug. Still, the inference by appearing in this kind of publication, at least to me, is inescapable that they are intending these drugs for distribution.

Senator HUMPHREY. Excuse me for interrupting, the High Times is a drug-oriented publication that promotes drug use, but those same kinds of advertisements appear also in such magazines as Playgirl, National Enquirer, so it isn't just the drug-culture magazines, but magazines purchased by the general population.

Mr. HAISLIP. That is correct, Senator, and I think that that poses a particularly difficult aspect of the act-alike problem. This product appears to be about the same as products that you can obtain in any drugstore. This morning, before coming to the hearing, I went to the drugstore. Here is a package of stimulants that contains caffeine, which is a typical ingredient of the look-alike; here is a package of weight-loss tablets. Now, if you look at the package that is genuine, it looks exactly like a drug called Dexamyl, which is an amphetamine controlled substance.

So the problem that we have is how to differentiate between the availability and extent of the various distributors. This is the diffi-

culty that we will face in adopting any legislation, and I suggest to you that there are a limited number of approaches available to us. We can restrict the products, but there we may find the difficulties of dealing with products which have been legitimately available. We can perhaps restrict the method by which the products are obtained. We know, for example, that the people that seem to be appealing to the drug abuse market primarily deal through mail order business. We could restrict the customer perhaps by some sort of age regulation.

Well, these are some of the approaches that could be considered, but it is not going to be an easy problem to deal with. It makes no sense to ask our police officers at the Federal, State, or local level to go about conducting investigations at the high school or street level if we are going to allow these pills to be manufactured and marketed.

So it seems to me that we must strike to the heart of the problem that we see, which is that a lot of people are trying and succeeding in getting very wealthy by appealing to the loopholes in the law.

[The prepared statement of Mr. Haislip follows:]

STATEMENT OF

GENE R. HAISLIP
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL

DRUG ENFORCEMENT ADMINISTRATION
U. S. DEPARTMENT OF JUSTICE
WASHINGTON, D.C.

Chairman Humphrey and Members of the Subcommittee on Alcoholism and Drug Abuse:

Thank you for this opportunity to provide you with DEA's views on the problem of look-alike drugs. Over the past two years much has been done at the federal and state levels to attempt to bring this activity under control. From DEA's perspective, these initiatives have had a significant impact on the look-alike problem. The precipitous growth of this phenomenom seen in 1980 and 1981 has been arrested and, in a number of areas, there has been a substantial decline in the availability of look-alikes. I hasten to add however that a problem remains, albeit in a different form. We are faced with a dynamic situation in which some of those involved appear willing and capable of adapting rather than going out of business. Because of the combined Federal and State attack, the look-alike industry has changed considerably over the past two years; so much so that if legislation were passed based on the problem as it existed in 1981, most of today's problem would fall outside its scope. The changing nature of the problem makes its magnitude difficult to assess. Nevertheless, I will attempt to characterize the situation as I see it today and then describe the actions taken by DEA, their impact and our future direction.

Nature of the Look-Alike Problem

In spite of the sudden explosive growth of this problem, look-alikes have been around for a number of years. In the mid-seventies, an organization known as Peashooter was selling bogus amphetamines to truck drivers in many Southern states. The head of this organization eventually started his own company devoted solely to the production and distribution of look-alikes.

By 1980, this phenomenon had spread across the nation. By 1981 it was estimated that at least 10 companies were manufacturing look-alikes and over 200 wholesalers were distributing them. During 1979 and 1980 DEA laboratories analyzed 1462 exhibits and over 500,000 dosage units of look-alikes.

During this period the term look-alikes referred to tablets, capsules or other substances containing noncontrolled, over-the-counter (OTC) ingredients, which closely resembled well-known, highly abused controlled drug products. Distributors were advertising these products as the legal way to get high, directly implying that the look-alikes could be sold as controlled substances. The look-alikes were sold in containers without proper labels, warnings or descriptions of the contents. Quality control was virtually nonexistent. Unethical entrepreneurs were making huge profits by using loopholes in society's legal and regulatory apparatus to peddle drugs and the concept of drug abuse to the nation's youth.

In late 1981 the Federal and state governments became actively involved in the battle against look-alikes. Some of the regulatory loopholes were closed but unfortunately others were found. Today the problem we face refers predominantly to those products which, although not manufactured to closely resemble controlled drug products, are promoted in the same manner and contain the same ingredients as those resembling controlled products. Many of the look-alike products, at least at the manufacturer level, are now sold in properly labeled containers with appropriate warnings. Usually the active ingredients and their quantities are identified on the label. Many of the look-alikes bear trademarks which the manufacturers say prevent them from being confused with other products. Further some of the look-alikes are imprinted

with National Drug Code (NDC) numbers and have specific names. They are advertised as stimulants, diet aids, appetite suppressants, decongestants and sleep aids. Generally, the more recent generations of look-alikes are not overtly represented as controlled products.

Once these products reach the street, or retail level user, however, they may be removed from their labeled bottles and contain no warnings or precautions about their use. The message to the user is the same as with the original look-alikes: that drugs should be used for thrills and not solely for legitimate medical reasons. Despite all the publicity surrounding look-alikes, there appears to be a number of people who still perceive them to be real controlled substances. Still others who are well aware of the contents and effects of look-alikes, continue to abuse them. In either case these stimulants mimic the appearance or effects of amphetamine-type products and generally contain one or more of the following OTC ingredients: caffeine, ephedrine, pseudoephedrine and phenylpropanolamine. The depressant products mimic the appearance or effects of sedative or hypnotic drugs such as Quaalude, Valium and Librium and generally contain combinations of the following ingredients: acetaminophen, salicylamide, doxylamine and chlorpheniramine.

Although they are legitimately used as nasal decongestants, analgesics, or for the relief of cold, allergy or asthma symptoms, the look-alike ingredients can produce mild stimulant or depressant effects and have caused serious injury to those who ingest large quantities. Moreover, many use look-alikes along with alcohol. There have been several documented reports of cerebral hemmorrhage and severe hypertension associated with the use of stimulant look-alikes. Reactions to look-alikes may range from nervousness,

insomnia or drowsiness to tachycardia, sharp rises in blood pressure, cerebral hemmorrhage, cardiac arrhythmias and temporary psychotic episodes. Emergency rooms have reported many episodes of adverse reactions associated with the use of look-alikes or their ingredients. A number of deaths associated with look-alike use have been reported with caffeine intoxication as the likely cause of death. In 1981, a new category for look-alikes was established for the Drug Abuse Warning Network (DAWN) to help determine the extent of this public health problem. During the period June 1981, through March 1983, 92 emergency room mentions were attributed directly to substances reported as look-alikes with the majority involving drugs obtained by street buys. Furthermore, many of the emergency room visits attributed to amphetamines and speed may be the result of look-alike abuse. It is important to note, however, that during the entire year of 1982, 48 emergency room mentions were reported by DAWN compared to 43 during only 6 months of 1981. Thus far in 1983 only 1 report of an emergency room episode attributed to look-alikes has been recorded in DAWN.

In addition to the health hazards inherent in taking look-alikes themselves, the risk of serious drug overdose from real controlled substances is greatly increased for look-alike users who unknowingly consume equal numbers of a real controlled product. This is most troublesome when depressants are involved. Health care professionals in emergency rooms, poison control centers and drug abuse clinics may be deceived by these products. They are hampered in determining and providing appropriate medical care in drug overdose cases.

Perhaps most important of all, the advertising and distribution of look-alike drugs in any form gives the impression of societal acceptance of the use of drugs for recreational purposes. This counteracts the efforts of the many

drug abuse educational programs supported by government and public organizations. The look-alikes have helped to create a market for stimulant and depressant use. Children and others who wouldn't normally abuse drugs are introduced to look-alikes and told they're safe and legal. The end result of the look-alike phenomenon is a glamorization and legitimacy of the concept of recreational drug use, particularly among children. The use of psychoactive substances for mood alteration - - even in the form of look-alikes if condoned, can only further add to our national drug abuse problem.

DEA Initiative

Since look-alikes contain only noncontrolled substances, DEA has no specific jurisdiction over look-alike products under the Controlled Substances Act (CSA). Unfortunately, it appears that no single Federal agency has jurisdiction over all facets of this drug abuse problem. I am pleased to report, however, that there has been a high degree of cooperation among Federal agencies in sharing information and devising and implementing strategies to effectively combat the problem. Additionally, each agency involved, specifically DEA, FDA and the United States Postal Service has set up independent programs using current resources and within the framework of existing laws and regulations to attack the look-alike problem. The activities undertaken by DEA and an assessment of their impact to date are as follows:

1. Drafting of a Model Act for Concerned States to Adopt

In November 1981, DEA drafted and distributed to the states a Model Imitation Controlled Substances Act. A revised version was distributed in February, 1982. The Model Act makes it unlawful for anyone to manufacture, distribute, possess or advertise an imitation controlled substance. An

imitation controlled substance is defined as a noncontrolled substance which by overall dosage unit appearance or by representation made, would lead a reasonable person to believe that the substance is a controlled substance. At this time, 41 states have passed some form of legislation against look-alikes; another 8 states have legislation pending; 4 of the 41 covered states have additional look-alike legislation pending.

The DEA Model Act does cover products not resembling controlled products but promoted or represented in the same manner as those resembling controlled products. An informal survey conducted by DEA's Office of Diversion Control in the Spring of 1983 showed that those states reporting a decrease in the availability of look-alikes all have look-alike legislation. Delaware, the first state to pass look-alike legislation and equally important, to enforce it has reported a dramatic decrease in the availability of look-alikes. It is noteworthy that a recent FDA seizure of millions of look-alike dosage units occurred in Michigan, one of the few states without look-alike legislation. The impact of state look-alike legislation is encouraging.

For state legislation to be effective, however, it is essential that the laws be enforced and violators prosecuted, particularly at the manufacturer and distributor levels. DEA is aware of nine states which have reported prosecutions under their look-alike laws. The Alabama and Illinois look-alike laws have been challenged in court and both declared constitutional.

A somewhat similar situation occurred with the drug paraphernalia industry. DEA drafted model legislation in 1979 which has been adopted by 25 states as of September 1982, and has been successful in supressing this one time powerful industry. More than 20 Federal District Courts have upheld the

Model Paraphernalia Act. The look-alike legislation drafted by DEA is patterned after the paraphernalia legislation and gives local jurisdictions similar authority over look-alikes.

2. Preparation of Documentation Describing the Look-Alike Problem, its Dangers and Effects, for Use in Support of the Model Act.

Information packages have been distributed to DEA field offices for use by personnel who are requested to provide information or testimony in support of state look-alike legislation. DEA personnel have made presentations concerning look-alikes to state legislatures, professional organizations, law enforcement personnel and parent and community groups in an effort to encourage their support of state look-alike legislation. A number of articles concerning look-alikes have been written by DEA personnel and published in trade journals of the pharmaceutical industry.

3. Enlisting the Support and/or Action of the Legitimate Pharmaceutical Industry

In an effort to limit the availability of capsules used to manufacture look-alikes, DEA asked the three domestic capsule manufacturers to voluntarily refuse orders to suspected look-alike manufacturers. This effort appears to be successful in that the popular black/black and yellow/yellow capsules are in extremely short supply as indicated by look-alike advertisements. There is evidence that look-alike manufacturers have looked to foreign capsule producers for their supplies. Some of the foreign suppliers are subsidiaries of domestic capsule manufacturers. The foreign subsidiaries have instituted safeguards similar to those of the parent company. A domestic company informed us of

an order for 50 million black/black and yellow/yellow capsules placed to one of its foreign subsidiaries by a third party in the United Kingdom. It was determined that the order was by a United States look-alike firm who was unable to obtain these capsules domestically. The request was not honored.
DEA is aware of at least one domestic brokerage house who has ordered capsules from foreign sources for look-alike manufacturers in the United States. When confronted by DEA personnel this firm agreed to stop selling to the look-alike companies.

Industry cooperation and information exchange has also resulted in a successful lawsuit filed by a legitimate manufacturer of controlled substances against a look-alike producer for trademark infringement.

4. Fostering Intergovernmental Agency Cooperation and Providing Active Support to Other Agency Efforts

Because no single Federal agency has clear-cut jurisdiction over the look-alike problem, it was imperative that the relevant Federal agencies coordinate their efforts against look-alike drugs. DEA has taken the initiative to establish interagency governmental groups at both the policy making and working levels. Representatives of the Drug Enforcement Administration, the Food and Drug Administration, the Federal Trade Commission, U.S. Postal Service, the Internal Revenue Service, and the National Institute on Drug Abuse meet periodically to discuss the dynamics of the look-alike problem, to identify changing trends in distribution and abuse patterns, and to report on each agency's activities or need for interagency support. Additionally, DEA has supported the efforts of the U.S. Postal Service and the FDA by supplying intelligence and by providing laboratory analyses and expert testimony in

court against look-alike manufacturers and distributors. DEA has worked with the FDA and the U.S. Postal Service in an attempt to develop an effective and realistic Federal strategy. In furtherance of this effort DEA and FDA have sponsored a joint meeting of the state attorneys general for their input and ideas.

In order to ascertain the magnitude of the impact of the DEA, FDA, U.S. Postal Service and state government initiatives on the look-alike problem the DEA Office of Diversion Control reviewed DEA laboratory data for the period January, 1979 through March, 1983. This study showed that the number of look-alike exhibits and dosage units analyzed peaked in 1980 at 868 and 329,305 respectively. By 1982 there was a 55.8% decrease in the number of exhibits (383) and an 82.3% decrease in the number of dosage units (58,316) of look-alikes analyzed. (See figure 1)

The laboratory data further showed that during the period 1979 through 1981, over 75% of the look-alike exhibits were capsules. In 1982 and 1983 capsules and tablets each accounted for roughly 50% of the exhibits. (See figure 2) Further, black and yellow capusles, the most popular stimulant look-alikes, made up over 47% of the look-alike exhibits in 1979 and 1980 compared to 30% in 1981 and 24% in 1982. Additionally products such as 20/20's, U-Zoom's, and Capricorns began appearing in late 1981 and increased in 1982. The percentage of stimulant look-alikes containing the triple combination of caffeine, ephedrine, and phenylpropanolamine increased from 16.5% in 1979 to approximately 70% in 1981 and 1982. Following FDA's declaration in August, 1982 that this triple combination is a new drug and requires a New Drug Application prior to marketing, this combination was found

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in only 27% of the exhibits analyzed in the first three months of 1983. (See figure 3)

The above study shows that the DEA and other government initiatives, begun in late 1981, have significantly reduced the availability of look-alikes and that these look-alikes have been replaced with products not resembling or directly represented as controlled products but containing some of the same ingredients as the original look-alikes.

These findings were reinforced at a meeting between DEA, FDA and the U.S. Postal Service and a group of state attorneys general. This meeting was held to discuss the status of the look-alike problem and what further state and federal regulations or criminal sanctions could be brought to bear on this problem. Representatives from 6 states were present. In general they were pleased with the efforts of the government agencies in reducing the look-alike problem but also concerned about the transition to products not resembling controlled drugs. They encouraged federal involvement in the look-alike battle but only to the extent that resources allow and would not be taken away from more serious drug abuse problems.

The state representatives and federal agencies agreed to work closely together and to use and expand existing authorities to combat the changing look-alike problem. Further, although the state representatives agreed that much of the problem can be and has been handled at the state level, the federal agencies agreed to continue to explore new approaches.

I know the need for federal legislation in response to the look-alike problem is of interest to this subcommittee. Further legislation is among the options we have considered in determining future strategies. A number of

things must be kept in mind when considering new legislation. First, much has been done using existing means at the federal level and through new and existing state laws. Because of these actions the problem has changed and we believe decreased. Secondly, the products in question are now very similar to those legitimately marketed diet aids and stimulants sold in most drug stores. For the purposes of a criminal statute, it would be extremely difficult to define the offenses in such a way which would separate the so called look-alikes from legitimate over-the-counter diet and sleep aids.

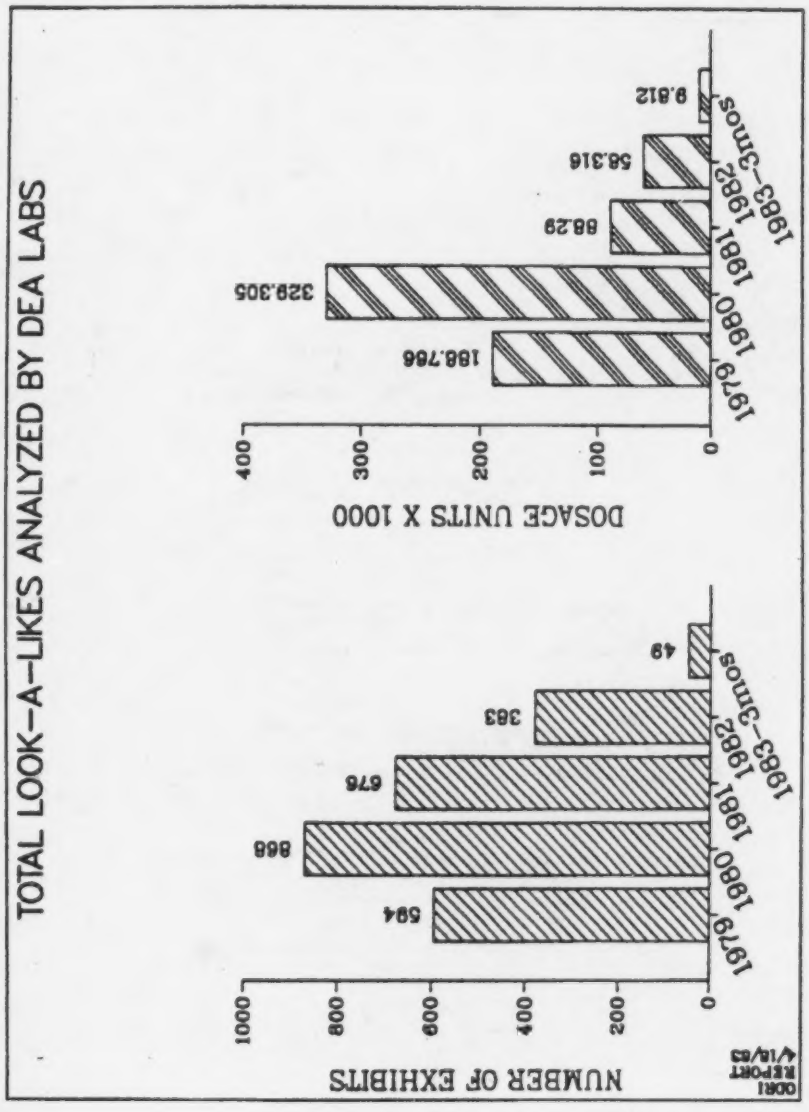
The problem as it exists today simply does not lend itself to conventional federal criminal legislative measures which would eliminate the manufacturing and distribution of these products. DEA's Model Imitation Controlled Substances Act or similar legislation can already be used by states to adequately control the problem at the street or retail level where the pills are removed from labeled containers and represented to be controlled products or where manufacturers and distributors market true look-alikes.

The nature of the present problem is the manufacture and marketing of products which in and of themselves appear legitimate but are distributed and promoted by unconventional means, such as their advertisement in drug abuse oriented publications, which have the effect of encouraging their abuse. There are a limited number of ways in which such a problem may be attacked. One may restrict either the product, the method of marketing or the authorized consumer. In this case the drugs themselves do not now appear to satisfy the criteria necessary for control under the Controlled Substances Act. If this were done many products now legitimately available in pharmacies would undoubtedly be greatly curtailed. The same result would most likely occur if they were placed on prescription status.

Yet another approach would be to prohibit mail order sales, sales in certain kinds of establishments or sales to minors. All of these approaches would greatly impact on the marketing of products, such as diet aids, caffeine "alert" pills, or sleep aids, which have heretofore been accepted for unrestricted marketing to the public.

If this analysis is correct, we are left with the difficult choice of determining whether or to what extent new restrictions should be imposed on psychoactive over-the-counter products in order to eliminate the abuses with which we are concerned. In as much as this is a relatively new phenomena, it has not been much considered in determining over-the-counter drug policies. We need to consider what kinds of drug products should be made available for unsupervised public purchase and consumption.

Be assured that DEA does consider the look-alike industry, even in its modified form, as a contributor to the drug abuse problem. As such we will continue to work together with other federal agencies and states within the scope of our existing statutory authority to help further reduce this problem.


TOTAL LOOK-A-LIKES ANALYZED BY DEA LABS
NUMBER OF EXHIBITS
1000
800
600
400
200
0
594
868
676
383
49
1979
1980
1981
1982
1983-3mos
DOSAGE UNITS X 1000
400
300
200
100
0
188,766
328,305
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1980
1981
1982
1983-3mos
ODR1
REPORT
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FIGURE 1

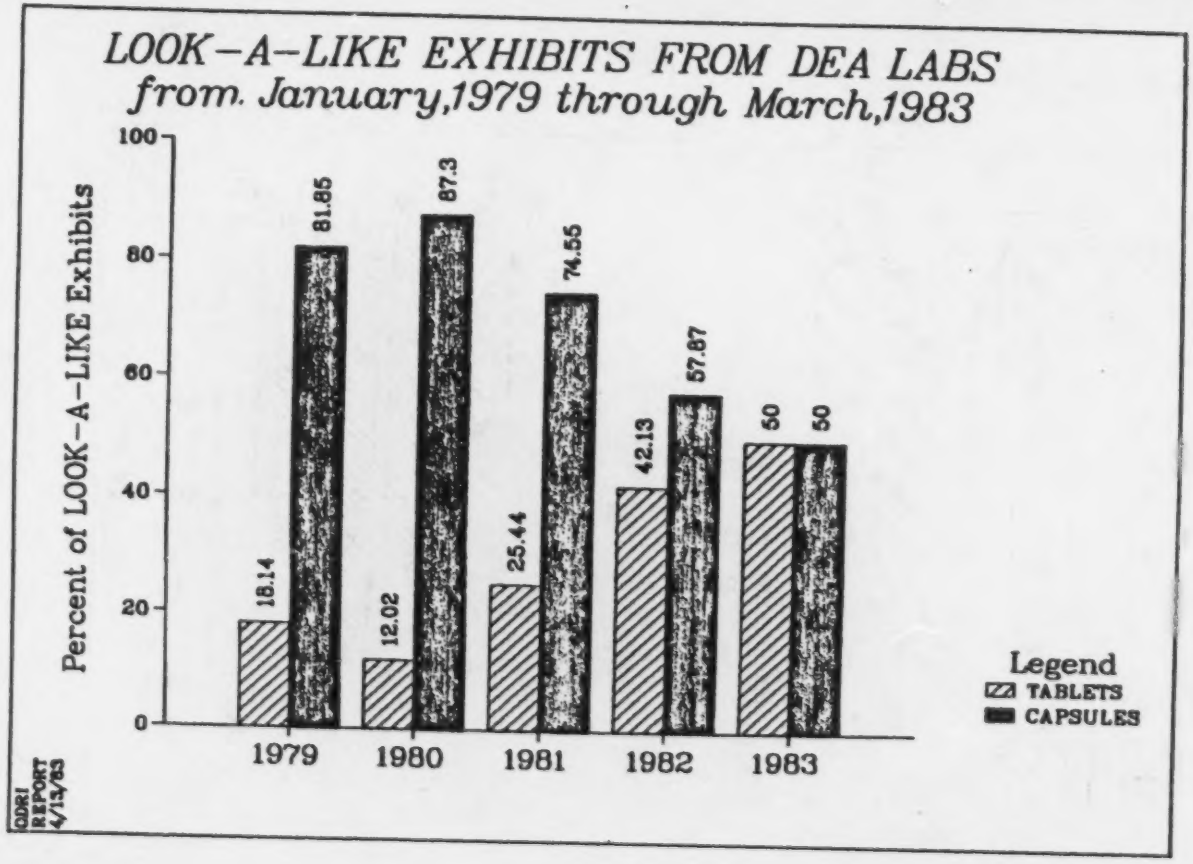
LOOK-A-LIKE EXHIBITS FROM DEA LABS
from. January,1979 through March,1983
Percent of LOOK-A-LIKE Exhibits
100
80
60
40
20
0
18.14
81.85
12.02
87.3
25.44
74.55
42.13
57.87
50
50
1979
1980
1981
1982
1983
Legend
TABLETS
CAPSULES
CDRI
REPORT
4/13/83

FIGURE 2

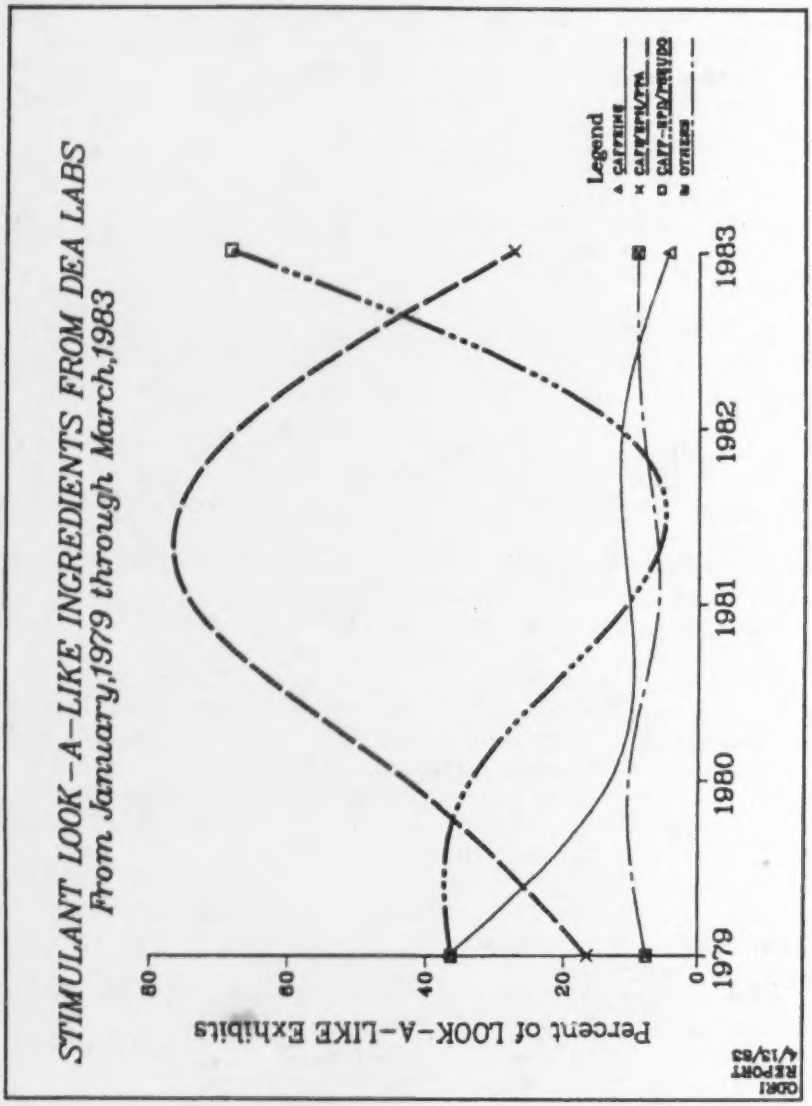
STIMULANT LOOK-A-LIKE INGREDIENTS FROM DEA LABS
From January,1979 through March,1983
Percent of LOOK-A-LIKE Exhibits
80
60
40
20
0
1979
1980
1981
1982
1983
Legend
CODE1
REPORT
4/13/83

FIGURE 3

Senator HUMPHREY. What does DEA think of the enforceability of the provision in the bill that I am offering that would make it unlawful to manufacture, distribute, and so on drugs that are intended for recreational use—and I know that making the determination whether or not it is for recreational use would be difficult. Can you comment on that?

Mr. HAISLIP. On the enforceability of such a law, I think that the difficulties of proof might make such a statute less than useful in some situations. As I went through my magazine on the way to the hearing here, I could see situations in which it might work, but others in which it wouldn't.

So I think the committee needs to pursue possible remedies of this sort, but I feel there are several problems that need to be focused on. That is why I tried to illustrate the similarity, almost identical nature, of some of these products which are available in every drugstore.

Maybe this suggests the question of who should be allowed to buy these medications, at what age, and for what purpose.

Senator HUMPHREY. Well, we know there are problems, but, at the same time——

Let's go on to Ms. Pedersen from the Federal Trade Commission. I note that your statement reflects only your own views, and that is rather odd. Are we not entitled to have the views of the FTC in this matter?

Ms. PEDERSEN. Let me explain, Mr. Chairman. The Federal Trade Commission is a regulatory agency that has five commissioners. On the look-alike drug situation, the activity has been at the staff level. The way the Commission operates is that the staff generates recommendations to the Commissioners for their consideration, adoption or rejection. This is the process used for individual cases, rulemaking, and other types of matters.

On many issues, Federal Trade Commission staff members such as myself will testify. We are required to state this disclaimer as part of our testimony to explain that the statement has not been adopted by the Commission.

Senator HUMPHREY. I understand that distinction. Is this statement representative of a general point of view, or——

Ms. PEDERSEN. Well, the Commission as a commission has not considered formal action related to look-alike drugs.

The views that I express are my own, but they are certainly my views as the Deputy Director of the Bureau of Consumer Protection, in charge of carrying out our responsibilities.

Senator HUMPHREY. So you have principal responsibility for consumer protection.

Ms. PEDERSEN. Yes.

Senator HUMPHREY. All right, will you proceed, then?

Ms. PEDERSEN. Yes, thank you. I would like to thank you for this opportunity to present my views on the problem of look-alike drugs and to comment on S. 497 and 503, two bills that were introduced by you, Chairman Humphrey.

Drug abuse through the use of look-alike drug products continues to present serious problems. By the term "look-alikes," I refer not only to the drugs that mimic the shape and color of controlled substances, and to drugs that are sold as though they were controlled

substances, but also to drugs that are offered explicitly or implicitly for unapproved mood-altering purposes.

Young people appear to be the target user group for these products. Although if taken in small doses the products are generally safe, they can be extremely harmful when they are abused. We understand that millions of these tablets and capsules are manufactured a week, with a potential for serious injury as a result.

Federal legislation to address this serious problem is needed and appropriate. The complex structure of the industry is only one contributing factor to the difficulty of remedying this problem. A second factor, as has been testified to previously, is that the market is apparently immune from currently available remedies.

The real problem with look-alike drugs is that they are available at all. This is not like the advertising or marketing of legitimate products, where the Federal Trade Commission has historically interceded to protect consumers and insure fair market behavior. There is no change that can be made in the advertisements for look-alike drugs to render them acceptable. If the problem is as serious as I understand it to be, businesses should not be allowed to promote or sell look-alike drugs at all. Similarly, there are no disclosures to require or unfair practices to prohibit that would make the marketing of these products acceptable. The marketing of these products through any means, deceptive or not, is itself troubling.

A ban at all levels—manufacture, distribution, and promotion—may be the only meaningful remedy. It is for this reason that I would support Federal legislation on look-alike drugs. Enactment of legislation that would put the look-alike drug industry out of business would be most welcome.

I would like to take this opportunity to present to the committee specific comments designed to clarify or strengthen the two bills that were introduced. These comments address only the substantive provisions of the bills, and take no position on the allocation of the enforcement responsibility.

As I understand the Chairman's proposals, one of the bills, the Imitation Controlled Substances Act of 1983, would forbid the manufacture and distribution of products that look like controlled substances if those products are marketed for the purpose of encouraging recreational drug use or any similar non-medical use. In addition, the bill would also outlaw products that are represented to be controlled substances, as well as products that purport to act like controlled substances.

In my view, this approach could have a dramatic impact on the numerous and varied ways that look-alike drugs are manufactured, advertised, distributed, and sold today. The bill would ban not only those drugs that mimic controlled substances, but also the non-look-alike products that purport to act like controlled substances. Prohibitions on the creation, manufacture, and distribution of these drugs offer an important restraint on the proliferation of these products.

We also know, however, that distributors of these products have been very creative in their efforts to avoid law enforcement. For example, we have seen national advertising for colorful diet pills with names that imitate controlled substances. Drugs may also be marketed in ways that encourage recreational drug use, but do not

contain any claims at all. Some drugs are simply offered for sale, and both buyers and sellers know that they are for mood-alteration purposes.

Where these products are advertised without alluding to their possible mood-altering properties, these advertisements may not violate the proposed legislation. The extent of coverage in the current proposal is limited by the requirement in section 308(a)(1) that the product "is marketed, sold, or distributed to encourage recreational drug use or abuse. * * *" Thus, violations may occur only if there are explicit or implicit claims of mood-alteration.

To eliminate effectively the look-alike drug problem, legislation should, if possible, reach all types of promotions. On the other hand, the legislation must be sufficiently narrow to avoid encompassing legitimately marketed diet aids and other generic drug products. In recommending that the committee consider this issue, I recognize the complexity of this area and encourage further study on this point.

Senator HUMPHREY. Do you have any specific ideas? We have been studying this for 2 years.

Ms. PEDERSEN. When you look at these advertisements, you see that one must draw the line very carefully. We do not want to recommend any action that may adversely affect the legitimate generic drug market. This is quite a difficult line to draw.

The second bill proposed by the Chairman would amend the postal statute to prohibit both the mailing of advertisements for look-alikes and the mailing of the drugs themselves. Because much of this trade appears to be by mail, prohibiting marketing and distribution should be an important weapon in combating continued sales.

Given the look-alike industry's practice of staying one step ahead of the law, a look-alike drug entrepreneur could set up a marketing system that avoids the Postal Service entirely by depending upon various alternative delivery systems. For this reason, the committee may want to consider legislation to prohibit the movement by any means of look-alike drugs in interstate commerce.

Finally, it is important to note that the bills currently before this committee are narrowly drawn and should have few, if any, adverse effects on legitimate businesses. There are exceptions for legitimate drugs and placebos used by physicians engaged in research. The definitions also appear to exempt the advertising and distribution of generic drugs. The availability of generic drugs, as has been mentioned, can be an important cost-controlling development in the health care area. I urge the committee to maintain this sensitivity to any potential anticompetitive effect in proposed legislation. The Federal Trade Commission staff is, of course, available to assist in any such analyses.

In conclusion, Mr. Chairman, let me once again emphasize my support for your efforts to end the availability of look-alike drugs. I believe that it is critical to enact legislation in order to deal effectively with this widespread national problem, and you have my full support for your efforts.

Thank you, and I would be pleased to answer any questions you may have.

[The prepared statement of Ms. Pedersen follows:]

STATEMENT OF

AMANDA B. PEDERSEN, DEPUTY DIRECTOR

BUREAU OF CONSUMER PROTECTION

FEDERAL TRADE COMMISSION

These remarks are the views of a member of the staff of the Federal Trade Commission and do not necessarily represent the views of the Commission or of any individual Commissioner.

Mr. Chairman and Members of this Committee:

I am Amanda B. Pedersen, Deputy Director of the Bureau of Consumer Protection at the Federal Trade Commission. Thank you for this opportunity to present my views on the problem of lookalike drugs and to comment on S.497 and 503, two bills introduced by Chairman Humphrey. These remarks reflect my own views as a member of the Federal Trade Commission staff, and do not represent the views of the Commission or any individual Commissioner.

Drug abuse through the use of lookalike drug products continues to present serious problems. By the term "lookalikes", I refer not only to drugs that mimic the shape and color of controlled substances, and to drugs that are sold as though they were controlled substances, but also to drugs that are offered explicitly or implicitly for unapproved mood-altering purposes.

Young people appear to be the target user group for these products. Although if taken in small doses the products are generally safe, they can be extremely harmful when they are abused. We understand that millions of these tablets and capsules are manufactured a week, with a potential for serious injury as a result.

A significant element in addressing the lookalike problem is the structure of the industry. There are basically four links to the distribution chain. At the top, there are companies that manufacture the gelatinous capsules, the vast majority of which are used for legitimate purposes. Also at this level are the manufacturers of the various chemical compounds that are the raw ingredients. The second tier consists of the encapsulators or tableters -- the companies that combine the raw ingredients and place them in capsules, or compress them into tablets. The third level is made up of the wholesalers that promote and sell the product in bulk, generally to other smaller distributors and occasionally to individuals for their own use. Finally, there are retailers who sell the product to ultimate customers. Although we are unable to estimate how many companies or individuals are involved at the third and fourth tiers, we believe that they are numerous and difficult to identify.

Federal legislation to address this serious problem is needed and appropriate. The complex structure of the industry is only one contributing factor to the difficulty of remedying this problem. A second factor, as has been testified to previously, is that the market is apparently immune from currently available remedies.

The real problem with lookalike drugs is that they are available at all. This is not like the advertising or marketing of legitimate products, where the FTC has historically interceded

to protect consumers and ensure fair market behavior. There is no change that can be made in the advertisements for lookalike drugs to render them acceptable. If the problem is as serious as I understand it to be, businesses should not be allowed to promote or sell lookalike drugs at all. Similarly, there are no disclosures to require or unfair practices to prohibit that would make the marketing of these products acceptable. The marketing of these products through any means, deceptive or not, is itself troubling.

A ban at all levels -- manufacture, distribution, and promotion -- may be the only meaningful remedy. It is for this reason that I would support federal legislation on lookalike drugs. Enactment of legislation that would put the lookalike drug industry out of business would be most welcome.

Chairman Humphrey has introduced two bills, S. 497 and S. 503, dealing with the lookalike drug industry. Let me take this opportunity to provide the Committee with specific comments designed to clarify or strengthen the bills. These comments address only the substantive provisions of the bills, and take no position on the allocation of enforcement responsibility.

As I understand the Chairman's proposals, one of the bills, the "Imitation Controlled Substances Act of 1983," would forbid the manufacture and distribution of products that look like controlled substances if those products are marketed for the

purpose of encouraging recreational drug use or any similar non-medical use. In addition, the bill would also outlaw products that are represented to be controlled substances, as well as products that purport to act like controlled substances.

In my view, this approach could have a dramatic impact on the numerous and varied ways that lookalike drugs are manufactured, advertised, distributed, and sold today. The bill would ban not only those drugs that mimic controlled substances, but also the "non-lookalike" products that purport to act like controlled substances. Prohibitions on the creation, manufacture, and distribution of these drugs offer an important restraint on the proliferation of these products.

We also know, however, that distributors of these products have been very creative in their efforts to avoid law enforcement. For example, we have seen national advertising for colorful diet pills with names that imitate controlled substances. Drugs may also be marketed in ways that encourage recreational drug use, but do not contain any claims at all. Some drugs are simply offered for sale, and both buyers and sellers know that they are for mood-alteration purposes.

Where these products are advertised without alluding to their possible mood-altering properties, these advertisements may not violate the proposed legislation. The extent of coverage in the current proposal is limited by the requirement in Section

308(a)(1) that the product "is marketed, sold, or distributed to encourage recreational drug use or abuse. . . ." Thus, violations may occur only if there are explicit or implicit claims of mood-alteration.

To eliminate effectively the lookalike drug problem, legislation should, if possible, reach all types of promotions. On the other hand, the legislation must be sufficiently narrow to avoid encompassing legitimately marketed diet aids and other generic drug products. In recommending that the Committee consider this issue, I recognize the complexity of this area and encourage further study on this point.

The second bill introduced by the Chairman would amend the postal statute to prohibit both the mailing of advertisements for lookalikes and the mailing of the drugs themselves. Because much of this trade appears to be by mail, prohibiting marketing and distribution should be an important weapon in combating continued sales.

Given the lookalike industry's practice of staying one step ahead of the law, a lookalike drug entrepreneur could set up a marketing system that avoids the Postal Service entirely by depending upon various alternative delivery services. For this reason, the Committee may want to consider legislation to prohibit the movement by any means of lookalike drugs in interstate commerce.

Finally, it is important to note that the bills currently before this Committee are narrowly drawn and should have few, if any, adverse effects on legitimate businesses. There are exceptions for legitimate drugs and placebos used by physicians engaged in research. The definitions also appear to exempt the advertising and distribution of generic drugs. The availability of generic drugs can be an important cost-controlling development in the health care area. I urge the Committee to maintain this sensitivity to any potential anticompetitive effect in proposed legislation. The Federal Trade Commission staff is, of course, available to assist in any such analyses.

In conclusion, Mr. Chairman, let me once again emphasize my support for your efforts to end the availability of lookalike drugs. I believe that it is critical to enact legislation in order to deal effectively with this widespread national problem, and you have my full support for your efforts.

I would be pleased to answer any questions you or the other members of the Committee may have.

Senator HUMPHREY. Thank you, Ms. Pedersen. Dr. Cooper?

Dr. COOPER. Mr. Chairman, I appreciate your invitation to discuss the drug-abuse phenomenon of look-alike drugs in this country. NIDA's concern about the use of these substances is based on the significant developmental and health dangers which they pose, particularly to our young people. I also welcome the opportunity to describe activities we are currently undertaking in response to this problem.

Since our last opportunity to testify before Congress on this phenomenon, several things have changed. As Mr. Hile and Mr. Haislip have previously described this morning, there have been changes in the appearance and marketing of these drugs. However, the ingredients and the intent to distribute the drugs haven't changed. Neither have the consequences or potential risk of taking these drugs to the young people. Moreover, the prevalence of use and the consequences of consumption are increasing. I would like to describe that in a little more detail than is in my formal testimony.

Senator HUMPHREY. Also indicate, if you can, why your finding apparently differs from data shown on this chart in terms of usage or prevalence.

Dr. COOPER. Let me try to do that. Although the prevalence of drug use in general is still high, recent trend information reveals that with respect to a number of drugs, prevalence is beginning to decline. However, there are a few exceptions within certain classes of drugs. One of those classes of drugs is the stimulants. For instance, from our high school senior survey, we have data now to show, clearly show, that from 1979 until 1982, the lifetime prevalence of stimulant use is up from 24 to 36 percent.

Senator HUMPHREY. Would you define your terms?

Dr. COOPER. In terms of high school senior students, 24 percent responded affirmatively to having taken stimulants some time in their life. Moreover, there is evidence to suggest that 20 percent of this increase is secondary to the look-alike phenomenon.

More specifically, in 1982, in the same survey, the methods for asking these questions were modified so that we could actually get information to determine actual prevalence of the use of look-alikes.

In this situation, 15 percent of the youths said they had used look-alikes some time in their life. Equally important, 6 percent said they used in the last month.

I would like to address the public health problems associated with the look-alike abuse. In general, there are two areas worth mentioning. These are the developmental problems in young people, and the physical or adverse consequences resulting from taking the drug.

With regard to the first, I am concerned that school children and others who don't normally abuse drugs are introduced to the look-alikes, and they are told that they are legal and safe. This whole issue of perceived harmfulness is very important.

A related issue in the developmental area for the maturing adolescent, is the easy availability of the legal highs increase the likelihood of developing a pattern of using drugs as a shortcut to pleasure, an artificial coping mechanism, and a substitute for satisfac-

tion achieved from realistic pleasures. These drugs can be used as steppingstones to the use of other drugs or contribute to making the drug experience an increasingly important or central part of your life.

Now, with respect to the adverse consequences or physical consequences, Mr. Hile and you have already stated that—basically these drugs are sympathomimetic drugs. However, these drugs are weak stimulants in relationship to amphetamines; therefore, in order to get the desired central nervous system effect, you have to take more of the drug. And that is where the other potential danger lies. At these higher doses levels, the cardiovascular system is under considerable stress and may fail in susceptible individuals. This accounts for the additional consequences, the strokes, the hypertension, the deaths that have been reported.

I would like to now turn to the NIDA responses to this problem, and highlight the three basic areas; research, education, and prevention.

In the area of research, one of the things we have done is modify the national survey so that we can get better understanding and more accurate estimates of actual prevalence of consumption. I also should indicate that a number of grants have been awarded which will attempt to better understand the self-administration and the reinforcement effects of these various look-alike combinations.

The other thing that we have done in attempt to better understand the morbidity and mortality data is to notify and to provide all the emergency rooms and medical examiners' offices that report to the DAWN system, a listing of the markings of these substances, so that when they see them, instead of reporting them as a black beauties or speed, they will report them as a look-alikes.

The other areas that I wanted to mention are in health education and drug abuse prevention. Consistent with that mission, we gave priority last year to alerting the professional community and the general public to the look-alike problem. A NIDA fact sheet on these substances which I believe is part of the testimony, was sent to hospitals, drug abuse treatment programs, State agencies, and a variety of other public and private sector agencies. Parenthetically, let me add that NIDA is currently updating that fact sheet to incorporate some of the other evolving phenomena that have been described this morning.

We are currently working with the American Medical Association in exploring mechanisms for putting information about drugs of abuse, including these drugs, and their associated health consequences, into the information data bank being developed right now by the AMA.

Because we believe the media play an important role in the area of public education and can influence the perceived harmfulness of these drugs, NIDA has for the past several years collaborated with the Scott Newman Foundation in the development of an award for television programers who broadcast shows with a strong drug prevention theme. Two of the programs awarded last year went to writers and producers who dealt with the dangers of the look-alike drugs. The writers of these shows received technical assistance from NIDA during the research and developmental phase.

Information on the look-alikes is also being included in a media campaign to publicize the health consequences of drug abuse. This campaign was planned by the Ad Council with the Institute's assistance and will be launched in September of this year.

In its overall prevention activities, NIDA has been working closely with the concerned parents movement since its inception several years ago. We have provided information and technical assistance to parent groups in their efforts to have State and local legislation passed which would control the use of look-alike drugs. Last year, four regional family workshops were convened by NIDA in order to allow parent groups to communicate and cooperatively develop drug abuse prevention approaches. We included in that forum as a specific agenda item, workshops on the look-alike drugs.

One other item not in the testimony, is something I think worth adding. In the last month NIDA has installed an 800 line for the convenience of the public and the drug abuse prevention field. Requests for assistance and for materials on look-alikes can be provided in a timely manner or referred to other NIDA staff with appropriate expertise in dealing with the specific issue on the look-alikes.

In summary, Mr. Chairman, NIDA believes that the problems posed by the look-alike drugs are serious ones which must be addressed. These substances not only pose real dangers to the health of their users, but they may well also lead to the abuse of other more dangerous illicit drugs. We are especially concerned because the use of these particular drugs seems to be increasing when most drug use among teenagers is decreasing. For these reasons, NIDA appreciates the attention this hearing is focusing on the entire look-alike issue, and we will continue our efforts to improve data collection, research, public education, and prevention activities dealing with these drugs.

Thank you, and I would be happy to answer any questions.

[The prepared statement of Dr. Cooper follows:]

Statement of

James R. Cooper, M.D.
Assistant Director for Medical Affairs
National Institute on Drug Abuse
Alcohol, Drug Abuse, and Mental Health Administration
U.S. Public Health Service
Department of Health and Human Services

Mr. Chairman, I appreciate your invitation to discuss the drug abuse phenomenon of "look-alike" drugs in this country. NIDA's concern about the use of these substances is based on the significant developmental and health dangers which they pose, particularly to our young people. I also welcome the opportunity to describe activities we are currently undertaking in response to this problem, as well as our plans in this area.

I think it would be helpful at the outset to put the question of "look-alike drugs" in a larger context by describing current overall trends in drug use. Data from two important surveys, the 1982 High School Senior Survey and the 1982 National Household Survey, indicate that the use of many illicit drugs has declined, or is declining, significantly from the peak levels attained during the late 1970's. Specific figures from these two studies are summarized in the charts and tables included in Appendix A to this testimony.

Cigarette use has also declined substantially, though that decline seems now to have ended. Still, despite this generally good news, the drug abuse problem among Americans, and particularly among American youth, is far from being solved. It is still true that:

"Roughly two-thirds of all American young people use an illicit drug at least once before they finish high school, and more than one-third have illicitly used drugs other than marijuana.

*At least one in every sixteen high school seniors is actively smoking marijuana on a daily basis, and fully 20% have done so for at least a month at some time in their lives.

*About one in sixteen seniors is drinking alcohol daily, and 41% have had five or more drinks in a row at least once in the past two weeks.

*Some 30% of high school seniors have smoked cigarettes in the prior month, a substantial proportion of whom are daily smokers.

*One-third of Americans over age 12 have used marijuana, cocaine, heroin, or psychotherapeutic drugs for nonmedical purposes at some time during their lives, and approximately one in every five Americans have used one or more of these drugs during the past year.

These are truly alarming levels of substance use and abuse, whether by historical standards or in comparison with other countries. In fact, it appears that they still reflect the highest levels of illicit drug use to be found in any nation in the industrialized world.

Stimulants--including the "look-alikes"--are an important part of this overall, somewhat mixed, picture of drug use in this country. It should be noted that stimulant use seems to be increasing, just when the use of other drugs is declining. Before looking at current trend data on these substances, I would like to briefly describe what look-alikes are.

Several categories of drug products contribute to the look-alike drug problem. True look-alike drugs, whose sale and distribution has been outlawed in most States, mimic prescription stimulants and depressants. They look like prescription drugs such as amphetamines and methaqualone (Quaaludes) in their size, color, shape, or markings. The look-alike drugs which are promoted as "uppers," because of their amphetamine-like properties, generally contain one or more of the following nonprescription stimulants: caffeine, phenylpropanolamine (PPA), or ephedrine. Since the FDA acted to require an NDA for the triple combination, look-alike products now generally only contain two of the three usual ingredients. The look-alike drugs which are promoted as "downers," because of their tranquilizing effect, usually contain only antihistamines.

More recently, we have been seeing increasing amounts of pills which contain the same ingredients as the true look-alike stimulant drugs and have the same effects on their users, but which do not physically resemble controlled substances. Having created a market for legal stimulants, manufacturers and distributors have now found that it is not necessary to lure buyers by making these substances look like controlled substances. Thus, while these pills are sometimes referred to as "other imitation controlled substances," in fact they are not physical imitations of other controlled drugs.

A third category of products related to the look-alike drug problem are stimulants and depressants which do not require prescriptions. Most of these psychoactive substances are legitimately marketed and sold over-the-counter (OTC) as diet aides, "stay awake" pills, or sleep aids. They are not manufactured to deceive the public, and do not look like controlled substances.

However, these products contain some of the same ingredients (PPA, caffeine) in various combinations as do the true look-alikes and can be subject to the same kind of abuse.

In the past, look-alike drug products have been promoted by their manufacturers through college newspapers, handbills at truckstops, unsolicited literature from mail order firms, or through storefront operations often located near high schools or college campuses. Distributors promote the drugs as "100 percent legal" or "legal stimulants" and have even offered free samples through the mail. In some cases, the products are advertised by the street names for amphetamines and barbiturates (e.g., Black Beauties, Yellow Jackets, Speed, and White Crosses), and because of their physical appearance, the buyer may be led to believe that he or she is purchasing a controlled substance. Fortunately the increase in the number of States with "look-alike laws," coupled with the rash of negative publicity surrounding these drugs, has curtailed some of the more blatant advertising practices.

Although prevalance is difficult to measure, it is clear that the manufacture, distribution and use of look-alike stimulants has become a significant drug abuse problem in recent years. As measured, for example, by the annual High School Senior Survey, while stimulant use was fairly steady between 1975 and 1979 it then rose rapidly for 3 years (lifetime prevalence went from 24% in 1979 to 36% in 1982), while most other drugs were starting to decline in popularity. Even though survey questions used were specifically asking about prescription-controlled amphetamine use, recent survey data indicate that as much as 20 percent of this increase may have been attributable to the use of look-alikes.

This past year was the first time the prevalence of the several classes of nonprescription stimulants could be estimated. Lifetime prevalence for the look-alikes is placed at 15%; monthly prevalence at 6%; and daily prevalence at 0.6%.

In addition, OTC diet pills have been used by a sizeable proportion of high school seniors (30% have used them at least once and 10% have used them in the prior month), with use being particularly high among females. OTC stay-awake pills are used by fewer seniors; 19% have ever used them and 6% have used them in the last month. Questions on OTC diet pills and OTC stay-awake pills did not refer to non-medical or recreational use. Thus these data reflect only exposure to stimulants.

We are very concerned about the dangers associated with look-like drugs. In addition to the fact that these drugs, while legal, are readily abusable, the highs they provide can act as stepping stones to the use of other drugs or contribute to making the drug experience an increasingly important or central part of life. Look-alikes and other OTC stimulants and depressants pose a significant developmental danger for young people. For the maturing adolescent, the easy availability of legal highs increases the likelihood of developing a pattern of use of drugs as a shortcut to pleasure, an artificial coping mechanism, and a substitute for satisfaction derived from realistic achievement.

These imitation drugs have already had serious harmful physical and psychological effects, particularly on teenagers and children. Specifically,

* School children and others who don't normally abuse drugs are introduced to look-alikes and told they're legal and safe.

* Imitation drugs give the impression that real controlled substances are not as potent and dangerous as they really are. Individuals who have been purchasing look-alikes on the "street" may unknowingly obtain real amphetamines and take quantities sufficent to result in overdose. Conversely, individuals who have been abusing amphetamines may underestimate the potency of look-alike drugs, and take an excessive quantity, seeking the expected "kick," but undergoing a toxic reaction instead.

* The substances may present diagnostic problems for physicians and poison centers attempting to deal with critical emergency situations.

In terms of the actual physical effects, there have been several well documented reports of severe hypertension, with cerebral hemorrhages and death, associated with the use of look-alike drugs. Central nervous system and circulatory system reactions to caffeine, PPA, and ephedrine include insomnia, restlessness, and excitement, as well as hypertension and tachycardia. The administration of these drugs may cause adverse reactions similar to those experienced by amphetamine users, including anxiety, restlessness, weakness, throbbing headache, respiratory difficulty, and palpitations. However, the central nervous system effects of PPA and caffeine are less marked then amphetamines, and substantial quantities of this combination are required to produce the desired euphoric effects. At these high dose levels the cardiovascular system is under considerable stress and may fail in susceptible individuals.

One of the ways we gather information on the negative health consequences of drug use is through emergency rooms and medical examiners in NIDA's Drug Abuse Warning Network (DAWN). Although we do not anticipate a great number of specific look-alike mentions, the look-alike drug category has recently been added to the DAWN reporting system in order to monitor its relationship to overall patterns of drug use.

To date at least 14 deaths have been confirmed due to look-alike drugs, primarily associated with caffeine overdose. Twelve of the fourteen deaths occurred in females, ten of them less than 30 years old. As cited earlier, these look-alike drug overdose cases can be easily misidentified by emergency room personnel. A review of 12 of the look-alike deaths indicated that in seven of the cases the drug involved was originally thought to be a stimulant other than a look-alike.

Because of the increasingly clear dangers associated with these look-alike drugs, NIDA has responded in several ways. First, we have participated in and provided information to a number of Federal groups assessing the nature and extent of the look-alike problem. One such Interagency Task Force, chaired by DEA and including representatives from NIDA, the FDA, the Postal Service, the IRS, and the Federal Trade Commission, is charged with looking at strategies for control of these substances, as well as with the problems they are posing.

NIDA also formed its own in-house task force on look-alikes last year in order to develop a plan for responding to the look-alike problem. A number of specific initiatives were subsequently undertaken. These included:

•Developing comprehensive information on the nature and extent of the look-alike and amphetamine abuse phenomenon, improving present data collection efforts and approaches where necessary;

•Developing and updating research knowledge on all drugs in this group.

During the past year, NIDA has initiated improved data collection procedures regarding these substances. For example, the 1982 High School Senior Survey, cited earlier, for the first time specifically distinguished between amphetamines and "look-alikes." NIDA also sent out an alert on the nature and extent of the health consequences and other problems associated with "look-alikes" to the hospital emergency rooms and medical examiners reporting to DAWN. This alert contained a listing of all the known markings used to identify look-alikes and was designed to help DAWN reporting units more accurately report morta ity and morbidity data associated with these substances.

NIDA's most important mission is in the area of health education and drug abuse prevention. Consistent with that mission, we gave priority last year to alerting the professional community and the general public to the "look-alike" problem. A NIDA capsule--or fact sheet--on these substances was sent to hospitals, drug abuse treatment programs, State drug abuse agencies, community mental health centers, and several other public and private sector agencies. In addition, we are currently working with the American Medical Association (AMA) to determine ways of best alerting the medical community; specifically, we are exploring the mechanisms for putting information about drugs of abuse (including

"look-alikes") and their associated health consequences, into the drug information data bank being developed by the AMA.

Because we are aware that the media plays such an important role in the area of public education, NIDA has for the past several years collaborated with the Scott Newman Foundation in the development of an award for television programmers who broadcast shows with a strong drug prevention theme. Two of the programs awarded this year's Scott Newman Drug Abuse Prevention Award in November 1982 dealt with the dangers of look-alike drugs: "Quincy: Bitter Pill" and "WKRP in Cincinnati: Pills." The writers of these shows received technical assistance from NIDA during the research and development phase. Information on look-alikes is being included in a media campaign to publicize the health consequences of drug abuse. This campaign was planned by the Ad Council with the Institute's assistance and will be launched in September 1983.

In its overall prevention activities, NIDA has been working closely with the concerned parents movement since their inception several years ago. We have provided information and technical assistance to parent groups in their efforts to have State and local legislation passed which would control the use of "look-alike" drugs. Last year, four regional family workshops were convened by NIDA in order to allow parent groups to communicate and cooperatively develop drug abuse prevention approaches. We included the abuse of "look-alike" drugs as a specific agenda item in these workshops, which involved representatives from parent groups and State drug abuse agencies, as well as other public health officials.

In summary, Mr. Chairman, NIDA believes that the problems posed by the "look-alike" drugs are serious ones, which must be addressed and faced. These substances not only pose real dangers to the health of their users, but they may well also lead to the abuse of other more dangerous illicit drugs. We are especially concerned because, based on the information available to us, the use of these particular drugs seems to be increasing, when most drug use among teenagers is decreasing. For these reasons, NIDA appreciates the attention this hearing is focusing on the entire "look-alike" issue, and we will continue our efforts to improve data collection, research, public education, and prevention activities dealing with these drugs.

Thank you. I would be happy to answer any questions you might have.

FACT SHEET
National Household Survey on Drug Abuse
National High School Senior Survey

National Household Survey on Drug Abuse

The National Household Survey on Drug Abuse is conducted every 2 or 3 years from a national sample of American households to assess the use of licit and illicit drugs for nonmedical purposes by the general population, age 12 years and older.

- The survey has been conducted under contract for the National Institute on Drug Abuse (NIDA) by the Social Research Group at the George Washington University since 1971. Senior Investigator is Ira H. Cisin, Ph.D. The 1982 survey is the seventh survey in the series.
- The survey involved 5,624 individuals in 1982.
- The survey sampled three populations: Youth (age 12-17 years), Young Adults (age 18-25 years), and Older Adults (age 26 and older).
- The random sample includes more females than males in the young adult and older adult cohorts.

High School Senior Survey

The High School Senior Survey is conducted annually from a national sample of high school seniors concerning their use of drugs and their attitudes toward drug taking.

- The survey has been conducted under a NIDA grant by the University of Michigan Institute for Social Research since 1975. Senior Investigator is Lloyd Johnston, Ph.D.
- The 1982 survey involved 17,700 high school seniors from public and private schools.
- Male and female participants are evenly distributed in the sample.

Measures of Drug Use

Both surveys use the following measures to determine prevalence of drug use:

- "Ever Used" (Lifetime Prevalence): used one or more times in a lifetime.
- "Current Use" (Use in Past Month): used at least once in the 30 days prior to the survey interview.

NATIONAL HOUSEHOLD SURVEY ON DRUG ABUSE

The following tables show the percentage of Americans who have used drugs of abuse. These numbers were gathered in a nationwide survey of households conducted in 1982 for the National Institute on Drug Abuse by the George Washington University Social Research Group.

LIFETIME PREVALENCE OF DRUG USE: 1972-1982

	Youth: age 12-17						Young Adults: age 18-25						Older Adults: age 26 +					
	'72	'74	'76	'77	'79	'82	'72	'74	'76	'77	'79	'82	'72	'74	'76	'77	'79	'82
Marijuana	14.0%	23.0%	22.4%	28.0%	30.9%	26.7%	47.8%	52.7%	52.9%	59.9%	68.2%	64.1%	7.4%	9.9%	12.9%	15.3%	19.6%	23.0%
Hallucinogens	4.8	8.0	5.1	4.8	7.1	6.2	-	15.8	17.3	19.8	25.1	21.1	-	1.3	1.8	2.8	4.5	6.4
Cocaine	1.5	3.8	3.4	4.8	5.4	6.5	9.1	12.7	13.4	19.1	27.5	28.3	1.6	.9	1.8	2.6	4.3	8.5
Heroin	.6	1.0	.5	1.1	.5	**	4.6	4.5	3.9	3.6	3.5	1.2	**	.3	.5	.8	1.0	1.1
Nonmedical Use of:																		
Stimulants	4.0	6.0	4.4	5.7	3.4	6.7	12.8	17.0	16.4	21.2	18.2	18.6	3.0	3.0	5.6	4.7	5.8	6.2
Sedatives	3.0	6.0	2.8	3.1	3.2	5.8	10.8	15.0	11.9	18.4	17.0	18.7	2.8	2.8	2.4	2.8	3.5	4.8
Tranquilizers	3.0	3.8	3.3	3.8	4.1	4.9	7.6	10.0	9.1	13.4	15.8	15.1	5.8	2.6	2.7	2.6	3.1	3.6
Analgesics	-	-	-	-	3.2	4.2	-	-	-	-	11.8	12.1	-	-	-	-	2.7	3.2
Any Nonmedical Use	-	-	-	-	7.3	10.3	-	-	-	-	28.5	28.4	-	-	-	-	9.2	8.8
Alcohol	-	54.0	53.6	52.6	70.3	65.2	-	81.6	83.6	84.2	85.3	84.6	-	73.2	74.7	77.5	81.5	80.2
Cigarettes	-	52.0	45.5	47.3	54.1	49.5	-	68.8	70.1	67.6	62.8	70.9	-	55.4	64.5	67.0	63.0	70.7

- Not Available
** Less than one-half of 1 percent
Source: National Household Survey on Drug Abuse, 1982. National Institute on Drug Abuse.

C83-1(a)

Final Percentages
April 1983

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Alcohol, Drug Abuse, and Mental Health Administration

HIGH SCHOOL SENIOR DRUG USE: 1975-1982

The following table shows the percentage of high school seniors from the classes of 1975 through 1982 who have used drugs of abuse. These numbers were gathered in annual nationwide surveys conducted for the National Institute on Drug Abuse by the University of Michigan Institute for Social Research. The eight surveys involved more than 100,000 high school seniors from public and private schools.

	Ever Used								Daily Users							
	Class of								Class of							
	'75	'76	'77	'78	'79	'80	'81	'82	'75	'76	'77	'78	'79	'80	'81	'82
Marijuana	47%	53%	56%	59%	60%	60%	59%	59%	6%	6%	6%	10.7%	10.3%	8.1%	7%	6.3%
Inhalants	NA	10	11	12	13	13	13	13	NA	0.0	0.0	0.1	0.0	0.1	0.1	0.1
Amyl & Butyl Nitrites	NA	NA	NA	NA	11	11	10	10	NA	NA	NA	NA	0.0	0.1	0.1	0.0
Hallucinogens	16	18	14	14	14	13	13	13	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
LSD	11	11	10	10	10	8	10	10	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
PCP	NA	NA	NA	NA	13	10	8	6	NA	NA	NA	NA	0.1	0.1	0.1	0.1
Cocaine	8	10	11	13	15	15	17	16	0.1	0.1	0.1	0.1	0.2	0.3	0.3	0.2
Heroin	2	2	2	2	1	1	1	1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Opiates	9	10	10	10	10	10	10	10	0.1	0.1	0.2	0.1	0.0	0.1	0.1	0.1
Stimulants	22	23	23	23	24	20	22	26	0.5	0.4	0.5	0.5	0.6	0.7	1.3	1.5
Sedatives	18	18	17	16	15	15	14	15	0.2	0.2	0.2	0.2	0.1	0.2	0.2	0.2
Barbiturates	17	16	16	14	13	11	11	10	0.1	0.1	0.2	0.1	0.0	0.1	0.1	0.1
Methaqualone	8	8	9	8	8	10	11	11	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1
Tranquilizers	17	17	18	17	16	15	16	14	0.1	0.2	0.3	0.1	0.1	0.1	0.1	0.1
Alcohol	90	92	93	93	93	93	93	93	4.7	5.5	6.1	6.7	6.6	6.8	6.6	6.2
Cigarettes	74	75	76	76	74	71	71	70	28.9	30.0	30.0	27.8	26.4	21.3	20.0	21.1

	Used in Past Month								Used in Last Year							
	Class of								Class of							
	'75	'76	'77	'78	'79	'80	'81	'82	'75	'76	'77	'78	'79	'80	'81	'82
Marijuana	27%	29%	28%	27%	27%	24%	20%	20%	40%	45%	48%	50%	51%	49%	48%	44%
Inhalants	NA	1	1	2	2	1	2	2	NA	3	4	4	6	6	4	5
Amyl & Butyl Nitrites	NA	NA	NA	NA	2	2	1	1	NA	NA	NA	NA	7	6	4	4
Hallucinogens	4	5	5	4	4	4	4	3	11	8	8	10	10	8	8	8
LSD	3	3	3	3	3	3	3	3	7	6	6	6	7	7	7	6
PCP	NA	NA	NA	NA	3	2	1	1	NA	NA	NA	NA	7	4	3	2
Cocaine	6	6	6	6	6	6	6	6	9	9	9	11	12	12	12	12
Heroin	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Other Opiates	3	3	3	3	3	3	3	3	5	5	5	5	5	5	5	5
Stimulants	9	9	9	9	10	10	10	14	16	16	16	17	18	21	25	30
Sedatives	8	8	8	7	6	6	5	5	12	11	11	10	10	10	11	8
Barbiturates	6	6	6	5	5	5	5	5	11	10	9	8	8	7	7	6
Methaqualone	5	5	5	5	5	5	5	5	8	8	8	8	8	7	8	7
Tranquilizers	8	8	8	7	6	6	6	6	11	10	11	10	10	8	8	7
Alcohol	68	68	71	70	70	70	71	70	84	84	87	88	88	88	87	87
Cigarettes	37	36	38	37	34	31	30	30	NA	NA	NA	NA	NA	NA	NA	NA

NA indicates data not available
* indicates less than .5%

Terms:
Ever Used: Used one or more times.
Daily Users: Used 20 or more times in the month before survey.
Used in Past Month: Used at least once in the 30 days prior to survey.
Used in Last Year: Used in the 12 months prior to survey.

Note: Separate questions about the use of PCP (angel dust) and amyl and butyl nitrites (poppers) were not asked until 1979.

Source: *Student Drug Use in America: 1975-1982*, National Institute on Drug Abuse.

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C83-2 February 1983

NATIONAL HOUSEHOLD SURVEY
ON DRUG ABUSE, 1982
Summary of Selected Findings*

The 1982 National Household Survey on Drug Abuse among youth, young adults, and older adults indicates that since 1979 there has been a leveling off of the spread of marijuana use in the youth population, as well as a significant decline in the number of persons who currently use marijuana, alcohol, and various other drugs. By and large, the 1982 data represent a reversal of the upward trends in drug use charted by earlier surveys in this series throughout the 1970s.

Marijuana

The most recent data indicate a new stabilization or even a slight decrease in the number of young persons who are now trying marijuana. For example, in 1982, the percentage of youth aged 12 to 17 who have ever tried marijuana (27 percent) is slightly lower than was the case for their counterparts in 1979 (31 percent). This slight decrease or leveling off is in contrast to the pattern set by the surveys of the 1970s; in those years, successive youth cohorts typically reported greater experience with marijuana.

Similarly, the percentage of young adults (age 18 to 25) in the current survey who say they have tried marijuana (64 percent) is slightly lower than was the case for their counterparts in the 1979 study (68 percent). Again, the slight decline represents a divergence from earlier trends, which showed an increase in lifetime prevalence from 48 percent of young adults in 1972.

The percentage of young persons reporting past-year use of marijuana decreased significantly between 1979 and 1982. For 12- to 17-year-olds the decrease was from 24 percent in 1979 to about 21 percent in 1982. In the 18-to-25 age group, the decline was from 47 percent in 1979 to about 41 percent in 1982.

Trends in the "current prevalence" of marijuana use--that is, changes in the percent reporting use during the month prior to the survey interview--are more responsive to the most recent changes in patterns of behavior. Here, we find a more substantial decrease for youth as well as for young adults.

In the 1977 and 1979 surveys, nearly 17 percent of all 12- to 17-year-olds reported use during the month prior to interview; but by 1982 this figure had dropped to 11 percent. And whereas 35 percent of young adults reported past-month use in the 1979 survey (an all-time high), by 1982 this figure had dropped seven percentage points to 28 percent.

*From National Household Survey on Drug Abuse, 1982, National Institute on Drug Abuse.

The following are the key findings in this report:

- Marijuana has shown a pattern of consistent decline since 1979. While the proportion of seniors who have ever tried the drug has not changed much (60 percent in 1979 vs. 59 percent in 1982), current use has dropped considerably--from 37 percent in 1979 to 29 percent in 1982. Of most importance, however, is the decrease in daily or near-daily use. Between 1975 and 1978, daily marijuana use climbed rapidly and steadily from 6 percent to 11 percent of all seniors. Since 1978, however, there has been just about as precipitous a fall in daily use, as young people's concerns about the consequences of regular use have grown and peer acceptance has fallen. (Some 60 percent now attribute great risk to regular marijuana use, up from 35 percent in 1978; and three-quarters now think their friends would disapprove of such behavior.) This year, active daily use is back down to where it was in 1975, at 6.3 percent in 1982, or about one in every 16 seniors.

- Annual prevalence of cocaine use had more than doubled between 1975 and 1979 and had then levelled off between 1979 and 1981. In 1982 for the first time use began to decline, annual prevalence falling from 12.4 percent to 11.5 percent.

- Another drug which began to decline in popularity for the first year is methaqualone. Annual prevalence fell from 7.6 percent to 6.8 percent following an increase in use between 1978 and 1980 and a levelling in 1981.

- The use of PCP has dropped dramatically since it was first measured in 1979. Annual prevalence has fallen from 7.0 percent in 1979 to 2.2 percent in 1982. The use of LSD, on the other hand, has remained fairly steady since around 1977, although even LSD use appears to have dropped slightly in 1982. Annual prevalence stands at 6.1 percent.

- The use of the amyl and butyl nitrites (inhalants known by such street names as "poppers" and "snappers") declined appreciably between 1979, when they were first measured, and 1981. However, there was no significant change observed this year. Total inhalant use has shown a similar pattern of change.

-more-

Alcohol and Cigarettes

Among 12- to 17-year-olds, the percentage who used alcohol during the month prior to the survey interview dropped from 37 percent in 1979 to 26 percent in 1982. Among young adults, aged 18 to 25, the drop was from 76 percent in 1979 to 68 percent in 1982.* Current "daily" use of alcohol (use on 20 or more days during the past month) also declined in the young-adult group--from 10 percent in 1979 to 7 percent in 1982. This directly parallels the drop in current daily use of marijuana.

The prevalence of past month cigarette use among 12-17-year olds remained stable between 1979 and 1982, while among young adults (18-25 year olds) current prevalence dropped from 43 percent in 1979 to 38 percent in 1982. A similar decline for current use among older Americans (26 years and older) is also seen--37 percent for 1979 and 34 percent for 1982.

Hallucinogens, Heroin, Cocaine

Hallucinogens (including LSD, PCP, and peyote) followed the marijuana pattern of downward trends in the younger age ranges. Among young adults, the prevalence of current hallucinogen use went down from 4 percent in 1979 to 2 percent in 1982. The same pattern appears to hold for heroin, although low levels of reported use of this drug may reflect a tendency to deny stigmatized behavior. The 1979 to 1982 decrease may be exaggerated due to the fact that the two Household Surveys were conducted at different times of the year.

*Alcohol use remained steady from the early to mid-1970s. The appearance of a sharp increase between 1977 and 1979 may be explained at least in part by the change to the use of self-administered answer sheets for questions on alcohol use.

But the results from even the revised questions in 1982 are higher than those from the unrevised questions in all years prior to 1981. Thus, it appears that there was an increase in the use of amphetamines up through 1981--or at least in the use of what the respondents believe to be real amphetamines. It seems possible, though, that there was a subsequent decrease in amphetamine use in 1982, given the general downward trends in use of most other drugs and the decline in the active use of stimulants as measured by the unadjusted-question version. Nevertheless, this decline cannot be empirically documented until next year.

- The revised questions on amphetamine use indicate that, while the unrevised questions overestimate true amphetamine use to a moderate degree, the revised prevalence levels are still very high: lifetime prevalence, 28 percent; annual, 20 percent; monthly, 11 percent; daily, 0.7 percent.

- The prevalence of the several classes of nonprescription stimulants can be estimated for the first time this year. Lifetime prevalence for look-alike pseudo-amphetamines is 15 percent, monthly prevalence 6 percent, and daily prevalence 0.6 percent.

- Over-the-counter diet pills have been used by a sizeable proportion of seniors (30 percent lifetime prevalence and 10 percent in the prior month). Use is particularly high among females: 42 percent lifetime prevalence, 14 percent in the last month, 2.0 percent current daily use.

- Stay-awake pills are used by fewer seniors: 19 percent prevalence, 6 percent in the last month.

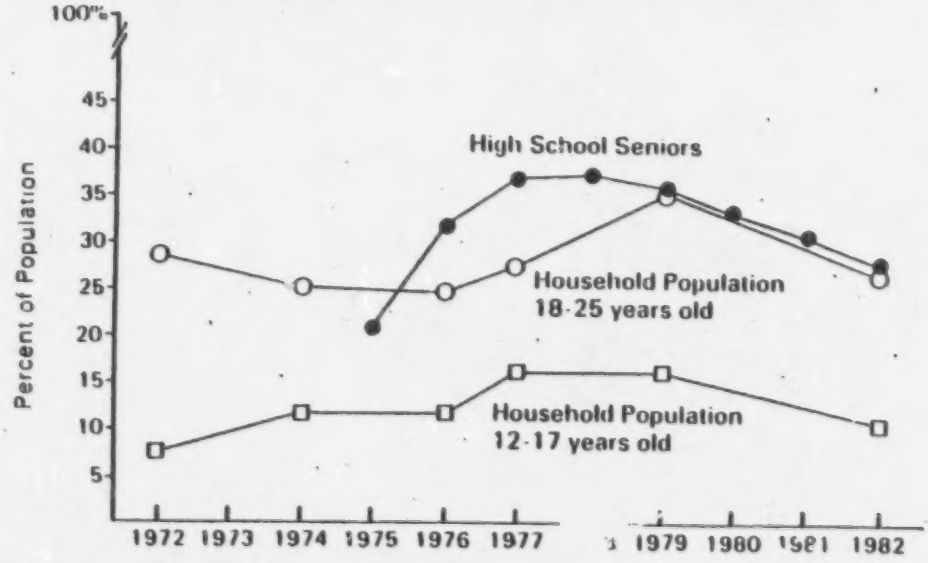
- The greater moderation by American young people in their use of illicit drugs may be found not only in the fact that fewer are using most types of drugs but also that use appears to be less intense. Since 1975 there has been a drop in the degree and/or duration of the "highs" reported by users for marijuana, stimulants, cocaine, sedatives, and opiates other than heroin.

- Alcohol use has remained relatively stable in this population since 1975, though at high levels. Nearly all young people have tried alcohol by the end of their senior year (93 percent) and the great majority (70 percent) have used it in the prior month.

Spectrum of Drug Use: 1982

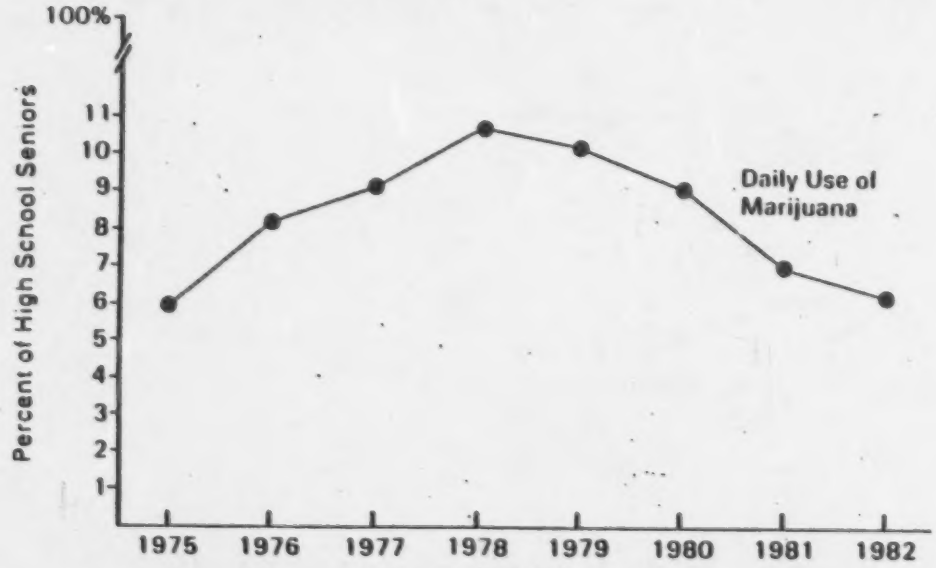
When the nonmedical use of psychotherapeutic drugs is combined in a single index together with the use of hallucinogens, cocaine, and heroin, it is found that about 40 percent of all young adults have had illicit experience with at least one substance other than marijuana; about 27 percent of this age group report past-year use of one or more of these "stronger" drugs. The corresponding figures for youth are: 14 percent tried one or more "stronger" drugs, and 10 percent have used during the past year.

Current Marijuana Use, U.S. Household Population and High School Seniors, 1972-1982



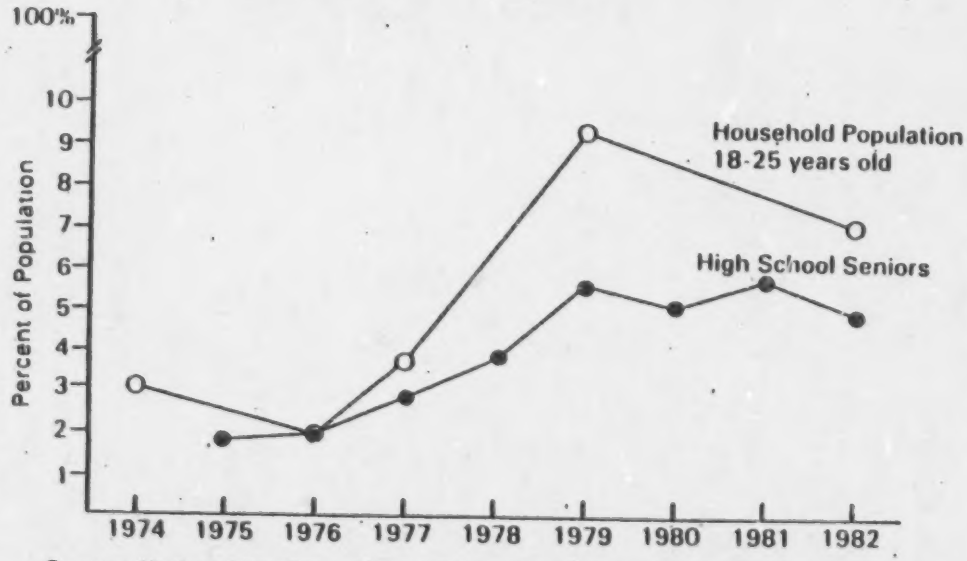
Source: National Institute on Drug Abuse, data from the *National Survey on Drug Abuse* and *Student Drug Use in America*, 1982.

Daily Marijuana Use, U.S. High School Seniors, 1975-1982



Source: National Institute on Drug Abuse, data from *Student Drug Use in America*, 1982.

Current Cocaine Use, U.S. Household Population and High School Seniors, 1974-1982



Source: National Institute on Drug Abuse, data from the *National Survey on Drug Abuse* and *Student Drug Use in America*, 1982.

Senator HUMPHREY. Thank you, Dr. Cooper. Mr. Nelson?

Mr. NELSON. Thank you, Mr. Chairman. I appreciate the opportunity to appear before this subcommittee to discuss the Postal Service's efforts to curtail the mail order sales and distribution of look-alike drugs.

We began our investigation of look-alike drugs in September 1980 after receiving complaints relating to what appeared to be the indiscriminate sale and distribution of controlled substances by mail. Typically, advertisements included full-color photographs of the drug products offered for sale and touted to the prospective purchaser the drugs' close physical resemblance to genuine controlled substances. The advertisements often claimed the products offered were 100-percent legal and 100-percent safe.

Samples of numerous look-alike drugs being distributed by mail were obtained and reviewed by medical experts. It was determined that they typically contained a combination of caffeine, ephedrine sulfate, and a third ingredient commonly referred to as PPA. Over-the-counter type products containing some of these ingredients, but not in this triple combination, are available without a doctor's prescription. However, dosage information and warnings restricting use by persons with particular medical conditions generally appear on products containing PPA, which, as has been stated before, is a common ingredient in diet preparations.

In a medical opinion, provided to the Inspection Service on products containing this triple combination of ingredients, Dr. Sorell L. Schwartz of the Department of Pharmacology, Georgetown University Medical and Dental Schools, stated they should "be considered a recognizable danger to public health." Of these particular ingredients, Dr. Schwartz warned that PPA was notably dangerous since it can cause elevation in blood pressure and exacerbate other cardiovascular disease.

Since the look-alike drugs did not actually contain controlled substances, we could not proceed criminally against the distributors. Nevertheless, because of the representations contained in the advertising and our evidence that such look-alikes were abused in the same ways as genuine controlled substances, the Postal Service took the position that look-alike drugs containing the triple combination were contrary to the advertiser's assertion that they were safe.

Based on what we believed were material misrepresentations in the advertising for look-alikes, administrative actions were initiated against the distributors under title 39, U.S.C., section 3005. Section 3005 permits the Postal Service, following procedures before an administrative law judge in conformity with the Administrative Procedure Act, to withhold and return to the sender mail addressed to anyone who is engaged in a scheme to obtain money or property through the mails by means of false representations. Between May 1981 and May 1982 the Postal Service filed 48 complaints alleging violations of title 39, U.S.C., section 3005.

In the complaints filed with the administrative law judges, we alleged that the principal distributors of these look-alike drugs made the following false representations in their advertisements:

One, the drug products involved may be safely used by the general population.

Two, the drug products involved are prepared, labeled, and marketed in accordance with the Federal food and drug laws.

The basic premise of these cases was the contention that the offered drug products resembled and were easily mistaken for other illegally trafficked drugs containing controlled substances. By language, pricing and other means, the promoters encouraged resale of the drugs by their customers to others. Thus, we believed the sellers were providing their customers, and encouraging them to use, the means to deceive others concerning the actual content of these drugs: The advertisements used street jargon to describe their products, such as "blue and clear," "brown and clear," "robin eggs," "714's," "black beauties," and "yellow jackets."

Many distributors have dropped most of their over-the-counter drugs that resemble genuine drugs of abuse. Many have dropped from their advertising the colored pictures of the items being offered for sale. Most have added cautions against use by persons with particular health problems or conditions and contain specific warnings against resale. There has been a marked reduction in the kinds of advertising cited in our earlier actions.

The Postal Inspection Service continues to monitor look-alike advertising and to investigate companies whose advertising appears to be false and misleading or to be in violation of the administrative orders and agreements which concluded our cases.

Thank you for the opportunity to appear before this subcommittee, and I would be happy to answer any questions.

[The prepared statement of Mr. Nelson follows:]

STATEMENT OF CHARLES P. NELSON
ASSISTANT CHIEF POSTAL INSPECTOR
BEFORE THE SENATE SUBCOMMITTEE ON
ALCOHOLISM AND DRUG ABUSE

JULY 14, 1983

MR. CHAIRMAN:

MY NAME IS CHARLES P. NELSON, AND I AM THE ASSISTANT CHIEF POSTAL INSPECTOR FOR CRIMINAL INVESTIGATIONS. I APPRECIATE THE OPPORTUNITY TO APPEAR BEFORE THIS SUBCOMMITTEE TO DISCUSS THE POSTAL SERVICE'S EFFORTS TO CURTAIL THE MAIL ORDER SALES AND DISTRIBUTION OF LOOK-ALIKE DRUGS.

I WOULD LIKE TO BEGIN BY TELLING YOU BRIEFLY ABOUT THE POSTAL INSPECTION SERVICE. THE POSTAL INSPECTION SERVICE IS THE INVESTIGATIVE AND AUDIT ARM OF THE UNITED STATES POSTAL SERVICE. WE HAVE INVESTIGATIVE JURISDICTION AND ENFORCEMENT RESPONSIBILITY OVER ALL VIOLATIONS OF FEDERAL LAW RELATING TO THE INTEGRITY AND SECURITY OF THE MAILS AND THE SAFETY OF ALL POSTAL VALUABLES, PROPERTY, AND PERSONNEL. OUR LAW ENFORCEMENT INVESTIGATIONS CONSIST OF TWO MAJOR CATEGORIES: CRIMINAL ATTACKS UPON THE MAILS, POSTAL FACILITIES, OF POSTAL EMPLOYEES, AND THOSE VIOLATIONS WHICH INVOLVE THE MISUSE OF THE POSTAL SYSTEM ITSELF SUCH AS MAIL FRAUD AND MISREPRESENTATIONS OF THE MAILING OF BOMBS, NARCOTICS, OR OTHER NONMAILABLE MATTER. WITH THAT INTRODUCTION, LET ME MOVE TO THE PURPOSE OF MY APPEARANCE.

WE BEGAN OUR INVESTIGATION OF LOOK-ALIKE DRUGS IN SEPTEMBER 1980 AFTER RECEIVING COMPLAINTS RELATING TO WHAT APPEARED TO BE THE INDISCRIMINATE SALE AND DISTRIBUTION OF CONTROLLED SUBSTANCES BY MAIL. TYPICALLY ADVERTISEMENTS INCLUDED FULL-COLOR PHOTOGRAPHS OF THE DRUG PRODUCTS OFFERED FOR SALE AND

TOUTED TO THE PROSPECTIVE PURCHASER THE DRUGS' CLOSE PHYSICAL RESEMBLANCE TO GENUINE CONTROLLED SUBSTANCES. THE ADVERTISEMENTS OFTEN CLAIMED THE PRODUCTS OFFERED WERE "100% LEGAL" AND "100% SAFE."

UNDER POSTAL REGULATIONS, CONTROLLED SUBSTANCES MAY ONLY BE MAILED BETWEEN PERSONS WHO ARE EITHER REGISTERED WITH THE DRUG ENFORCEMENT ADMINISTRATION OR WHO ARE EXEMPT FROM SUCH REGISTRATION.

SAMPLES OF NUMEROUS LOOK-ALIKE DRUGS BEING DISTRIBUTED BY MAIL WERE OBTAINED AND REVIEWED BY MEDICAL EXPERTS. IT WAS DETERMINED THAT THEY TYPICALLY CONTAINED A COMBINATION OF CAFFEINE, EPHEDRINE SULFATE, AND PHENYLPROPANOLAMINE, COMMONLY REFERRED TO AS "PPA." OVER-THE-COUNTER TYPE PRODUCTS CONTAINING SOME OF THESE INGREDIENTS, BUT NOT IN THIS TRIPLE COMBINATION, ARE AVAILABLE WITHOUT A DOCTOR'S PRESCRIPTION. HOWEVER, DOSAGE INFORMATION AND WARNINGS RESTRICTING USE BY PERSONS WITH PARTICULAR MEDICAL CONDITIONS GENERALLY APPEAR ON PRODUCTS CONTAINING PPA--A COMMON INGREDIENT IN DIET PREPARATIONS.

IN A MEDICAL OPINION PROVIDED TO THE INSPECTION SERVICE ON PRODUCTS CONTAINING THIS TRIPLE COMBINATION OF INGREDIENTS, DR. SORELL L. SCHWARTZ OF THE DEPARTMENT OF PHARMACOLOGY, GEORGETOWN UNIVERSITY MEDICAL AND DENTAL SCHOOLS, STATED THEY SHOULD "BE CONSIDERED A RECOGNIZABLE DANGER TO PUBLIC HEALTH." OF THESE PARTICULAR INGREDIENTS, DR. SCHWARTZ WARNED THAT PPA WAS NOTABLY DANGEROUS SINCE IT CAN CAUSE ELEVATION IN BLOOD PRESSURE AND EXACERBATE OTHER CARDIOVASCULAR DISEASE.

SINCE THE LOOK-ALIKE DRUGS DID NOT ACTUALLY CONTAIN CONTROLLED SUBSTANCES, WE COULD NOT PROCEED CRIMINALLY AGAINST THE DISTRIBUTORS. NEVERTHELESS, BECAUSE OF THE REPRESENTATIONS CONTAINED IN THE ADVERTISING AND OUR EVIDENCE THAT SUCH LOOK-ALIKES WERE ABUSED IN THE SAME WAYS AS GENUINE CONTROLLED SUBSTANCES, THE POSTAL SERVICE TOOK THE POSITION THAT LOOK-ALIKE DRUGS CONTAINING THE TRIPLE COMBINATION WERE CONTRARY TO THE ADVERTISER'S ASSERTION THAT THEY WERE SAFE.

BASED ON WHAT WE BELIEVED WERE MATERIAL MISREPRESENTATIONS IN THE ADVERTISING FOR LOOK-ALIKES, ADMINISTRATIVE ACTIONS WERE INITIATED AGAINST THE DISTRIBUTORS UNDER TITLE 39, U.S. CODE, SECTION 3005. SECTION 3005 PERMITS THE POSTAL SERVICE, FOLLOWING PROCEDURES BEFORE AN ADMINISTRATIVE LAW JUDGE IN CONFORMITY WITH THE ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. CHS. 5, 7), TO WITHHOLD AND RETURN TO THE SENDER MAIL ADDRESSED TO ANYONE WHO IS ENGAGED IN A SCHEME TO OBTAIN MONEY OR PROPERTY THROUGH THE MAILS BY MEANS OF FALSE REPRESENTATIONS. BETWEEN MAY 1981 AND MAY 1982 THE POSTAL SERVICE FILED 48 COMPLAINTS ALLEGING VIOLATIONS OF TITLE 39, U.S. CODE, SECTION 3005.

IN THE COMPLAINTS FILED WITH THE ADMINISTRATIVE LAW JUDGES, WE ALLEGED THAT THE PRINCIPAL DISTRIBUTORS OF THESE LOOK-ALIKE DRUGS MADE THE FOLLOWING FALSE REPRESENTATIONS IN THEIR ADVERTISEMENTS:

1. THE DRUG PRODUCTS INVOLVED MAY BE SAFELY USED BY THE GENERAL POPULATION.
2. THE DRUG PRODUCTS INVOLVED ARE PREPARED, LABELED, AND MARKETED IN ACCORDANCE WITH THE FEDERAL FOOD AND DRUG LAWS.

THE BASIC PREMISE OF THESE CASES WAS THE CONTENTION THAT THE OFFERED DRUG PRODUCTS RESEMBLED AND WERE EASILY MISTAKEN FOR OTHER ILLEGALLY TRAFFICKED DRUGS CONTAINING CONTROLLED SUBSTANCES. BY LANGUAGE, PRICING AND OTHER MEANS, THE PROMOTERS ENCOURAGED RESALE OF THE DRUGS BY THEIR CUSTOMERS TO OTHERS. THUS, WE BELIEVED THE SELLERS WERE PROVIDING THEIR CUSTOMERS, AND ENCOURAGING THEM TO USE, THE MEANS TO DECEIVE OTHERS CONCERNING THE ACTUAL CONTENT OF THESE DRUGS. THE ADVERTISEMENTS USED STREET JARGON TO DESCRIBE THEIR PRODUCTS SUCH AS "BLUE AND CLEAR," "BROWN AND CLEAR," "ROBIN EGGS," "714'S," "BLACK BEAUTIES," AND "YELLOW JACKETS."

OUR EVIDENCE SHOWED THAT THOSE PURCHASING LOOK-ALIKES--BOTH DIRECTLY FROM PROMOTERS AND STREET CORNER "PUSHERS"--WERE JUNIOR HIGH, HIGH SCHOOL, AND COLLEGE-AGE YOUNG PEOPLE. OF PARTICULAR CONCERN WAS EVIDENCE OF TRAFFICKING AND USE BY ELEMENTARY SCHOOL CHILDREN.

THE 48 ADMINISTRATIVE COMPLAINTS WE HAVE FILED RELATED TO LOOK-ALIKE DRUG DISTRIBUTORS LOCATED THROUGHOUT THE COUNTRY. WHILE I BELIEVE THE POSTAL SERVICE HAS DILIGENTLY PURSUED ITS RESPONSIBILITY IN THIS AREA, I MUST POINT OUT THE POSTAL SERVICE'S ADMINISTRATIVE AUTHORITY IN THESE INVESTIGATIONS IS LIMITED TO THE MAIL ORDER ASPECTS OF THESE BUSINESSES. WHILE INITIALLY OUR EFFORTS CURTAILED THE SALE AND DISTRIBUTION OF THESE PRODUCTS, MANY OF THE MAJOR PROMOTERS BEGAN CIRCUMVENTING THE MAIL STOP ORDERS AND CONSENT AGREEMENTS BY CONTINUING THEIR ACTIVITIES OUTSIDE THE MAILS. SOME CURRENT ADVERTISEMENTS TELL PROSPECTIVE CUSTOMERS THAT ONLY TELEPHONE ORDERS WILL BE ACCEPTED AND THAT PAYMENT MUST BE BY CREDIT CARD, BANK WIRE, OR UNITED PARCEL SERVICE C.O.D. THESE PROCEDURES REMOVE THE ORDERS AND EXCHANGE OF MONEY FROM THE U. S. MAIL, THEREBY AVOIDING POSTAL SERVICE JURISDICTION

UNDER THE FALSE REPRESENTATION STATUTE AND RENDERING ANY PREEXISTING MAIL STOP ORDER INEFFECTIVE.

MANY DISTRIBUTORS HAVE DROPPED MOST OF THEIR OVER-THE-COUNTER DRUGS THAT RESEMBLE GENUINE DRUGS OF ABUSE. MANY HAVE DROPPED FROM THEIR ADVERTISING THE COLORED PICTURES OF THE ITEMS BEING OFFERED FOR SALE. MOST HAVE ADDED CAUTIONS AGAINST USE BY PERSONS WITH PARTICULAR HEALTH PROBLEMS OR CONDITIONS AND CONTAIN SPECIFIC WARNINGS AGAINST RESALE. THERE HAS BEEN A MARKED REDUCTION IN THE KINDS OF ADVERTISING CITED IN OUR EARLIER ACTIONS.

IN INVESTIGATING THESE CASES WE WORKED WITH OTHER CONCERNED AGENCIES. WE PARTICIPATED WITH THE FOOD AND DRUG ADMINISTRATION, FEDERAL TRADE COMMISSION, AND THE DRUG ENFORCEMENT ADMINISTRATION IN AN INTERAGENCY GROUP STUDYING REMEDIES TO THESE PROBLEMS.

IN RETROSPECT, OUR ACTIONS AGAINST MAIL ORDER DISTRIBUTION OF LOOK-ALIKES MAY BE VIEWED AS A HOLDING ACTION. OUR EFFORTS HOPEFULLY GAVE FEDERAL AND STATE DRUG ENFORCEMENT AGENCIES AND LEGISLATIVE BODIES TIME TO INITIATE THEIR ACTIONS AND ENACT LEGISLATION CONCERNING THIS PROBLEM.

HOWEVER, THE POSTAL INSPECTION SERVICE CONTINUES TO MONITOR LOOK-ALIKE ADVERTISING AND TO INVESTIGATE COMPANIES WHOSE ADVERTISING APPEARS TO BE FALSE AND MISLEADING OR TO BE IN VIOLATION OF THE ADMINISTRATIVE ORDERS AND AGREEMENTS WHICH CONCLUDED OUR CASES.

WE ARE FAMILIAR WITH S. 503 AND S. 497. S. 503 IS SIMILAR TO S. 2736, WHICH WAS INTRODUCED IN THE LAST CONGRESS. IT WOULD MAKE IT UNLAWFUL TO

MANUFACTURE, DISTRIBUTE, OR POSSESS WITH INTENT TO DISTRIBUTE, A DRUG WHICH IS AN IMITATION OF A CONTROLLED SUBSTANCE. JURISDICTION TO ENFORCE THE PROPOSED STATUTE WOULD BE VESTED IN THE FOOD AND DRUG ADMINISTRATION. WHILE THIS BILL WOULD APPEAR TO PROVIDE POSITIVE ASSISTANCE IN THE GOVERNMENT'S EFFORTS TO CONTROL THIS PROBLEM, I WOULD DEFER TO FDA'S VIEWS CONCERNING ITS EFFECT UPON THAT AGENCY'S EFFORTS TO ADDRESS THIS PROBLEM.

S. 497 IS SIMILAR TO S. 2735, WHICH WAS ALSO INTRODUCED IN THE LAST CONGRESS. IT WOULD AMEND TITLE 39 TO MAKE "DRUG-ABUSE-ORIENTED ADVERTISEMENTS" AND SHIPMENTS OF "IMITATION CONTROLLED SUBSTANCES" NONMAILABLE AND AUTHORIZE THE POSTAL SERVICE TO SEIZE, DETAIN, AND DISPOSE OF SUCH MATTER WHEN FOUND IN THE MAILS. BASED UPON OUR PREVIOUS ANALYSIS OF S. 2735, WE BELIEVE S. 497 WOULD ENHANCE OUR ABILITY TO PREVENT MAIL ORDER SALES OF LOOK-ALIKE DRUGS. HOWEVER, BY VIRTUE OF CURRENT SECTION 3001(F) OF TITLE 39, THE POSTAL SERVICE CAN DISPOSE OF NONMAILABLE MATTER ONLY AFTER CONDUCTING ADMINISTRATIVE MAILABILITY PROCEDURES PURSUANT TO CHAPTERS 5 AND 7 OF TITLE 5. THESE PROCEEDINGS ALONE ARE OFTEN OF QUESTIONABLE VALUE AS A MEANS OF DISCOURAGING MAIL ORDER MARKETING DEEMED TO BE SOCIALLY UNDESIRABLE SINCE THEY CAN ONLY BE INITIATED AFTER THE CHALLENGED MATERIAL HAS ALREADY BEEN MAILED. MOREOVER, THE MAILER IS FREE TO CONTINUE TO MAIL SUCH MATTER UNTIL THE ADMINISTRATIVE PROCEEDING IS COMPLETED AND MAY CIRCUMVENT MAILABILITY ORDERS INDEFINITELY SIMPLY BY CHANGING ITS NAME AND ADDRESS.

AS WE SUGGESTED WITH RESPECT TO S. 2735, IT WOULD SEEM THAT A MORE EFFECTIVE BILL COULD BE CRAFTED BY AMENDING TITLE 39, U.S. CODE, SECTION 3005 TO MAKE THE MAILING OF "DRUG-ABUSE-ORIENTED ADVERTISEMENTS" AND "IMITATION CONTROLLED SUBSTANCES," AS THESE TERMS ARE DEFINED IN THE BILL, PRIMA FACIE

EVIDENCE THAT THE MAILER IS ENGAGED IN CONDUCTING A SCHEME OR DEVICE FOR OBTAINING MONEY OR PROPERTY THROUGH THE MAIL BY FALSE REPRESENTATIONS. IN 1978, CONGRESS AMENDED SECTION 3005 IN THIS FASHION IN ORDER TO DEAL MORE EFFECTIVELY WITH MAILINGS OF NONMAILABLE FALSE BILLS AND INVOICES. SEE PUB. L. 95-360, SEPT. 9, 1978, 92 STAT. 594. AN AMENDMENT OF THIS KIND WOULD ALSO ENABLE THE POSTAL SERVICE TO PROMPTLY CHALLENGE MAILINGS INVOLVING IMITATION CONTROLLED SUBSTANCES IN PROCEEDINGS UNDER SECTION 3007 OF TITLE 39. THIS SECTON PERMITS THE FEDERAL DISTRICT COURTS TO ISSUE TEMPORARY RESTRAINING ORDERS AND PRELIMINARY INJUNCTIONS TO DETAIN DELIVERY OF MAIL PENDING COMPLETION OF ADMINISTRATIVE PROCEEDINGS UNDER SECTION 3005. THIS INTERIM RELIEF IS NOT AVAILABLE IN PROCEEDINGS ARISING ONLY UNDER SECTION 3001.

THANK YOU FOR THE OPPORTUNITY TO APPEAR BEFORE THIS SUBCOMMITTEE. I WOULD BE HAPPY TO ANSWER ANY QUESTIONS.

Senator HUMPHREY. Thank you, Mr. Nelson. I believe each of the agencies represented here this morning is part of the task force that has called a meeting on this issue, is that not correct?

Mr. HAISLIP. Yes.

Senator HUMPHREY. How often have these meetings been held?

Mr. HAISLIP. I would like to respond to that. We have had meetings of all those represented here plus other representatives, and then we have had more frequent meetings, for operational purposes, between those of us who have some operational capability, especially the Postal Service, DEA, and the Food and Drug Administration. We have met at least once every 2 months.

Senator HUMPHREY. One of the problems we have is trying to find a volunteer agency, but no one seems to want to take on the responsibility, at least not more than a small part of it.

So we are going to have to settle on that somehow.

Let me ask Mr. Hile, is there authority already existing within statute giving you the authority to—what I am trying to get at is this business of the triple entity. Where did you get that authority?

Mr. HILE. That authority is in the act now.

Senator HUMPHREY. It's in there, but not double entity,

Mr. HILE. It may be for some double entity. That is something the agency is currently considering.

Senator HUMPHREY. It may be.

Mr. HILE. A new drug is a drug that is not recognized by experts who by training and experience have concluded that the drug is safe and effective.

Senator HUMPHREY. You say you are trying to determine it. How long is it going to take to make a determination?

Mr. HILE. The matter is currently under consideration.

Senator HUMPHREY. How long has it been under consideration?

Mr. HILE. The whole matter has been under consideration for some period of time, a couple of years since we took our first actions under the counterfeit provisions of the Food, Drug, and Cosmetic Act.

Senator HUMPHREY. This matter of whether you have the authority to bar double-entity drugs.

Mr. HILE. The authority is not so much the problem as whether or not the drugs are in fact new drugs. One must go through sufficient consideration of the prior use of those drugs, and——

Senator HUMPHREY. Practically speaking, when can we expect a decision, a finding, in this narrow area, whether you have the authority or whether these are new drugs, or whatever, a decision on whether you have got the authority to ban them?

Mr. HILE. I think we are reasonably near a decision, Mr. Chairman. We have been working very diligently on the matter for a number of months, following our initiatives on the triple combination. It was after that initiative that these other drugs began to appear in greater quantity.

And we are nearing our decisions in that regard. Whether or not we can apply our decisions to all of the drugs that are found in the look-alike problem or not is something else.

Senator HUMPHREY. You then put them on a controlled list, is that the mechanism?

Mr. HILE. They then become illegal in interstate commerce, and the products that are shipped in interstate commerce are then subject to seizure and those who manufacture those products and distribute them are subject to the injunctive provisions of our act, and ultimately to the criminal provision.

Senator HUMPHREY. It was the triple-entity classification that led to the removal of the phenylpropanolamine from most of these, was it not?

Mr. HILE. Well, it certainly has discouraged the manufacture of look-alike drugs that include caffeine, phenylpropanolamine, and ephedrine. We still are encountering look-alike drugs that include either caffeine and ephedrine or caffeine and phenylpropanolamine.

Senator HUMPHREY. Well, removal of one of the three elements rendered them significantly less potent, would that be correct, Dr. Cooper?

Dr. COOPER. That is one of the things we are trying to look at right now. It's potentially possible. There does appear to be at least preliminary data that would suggest that there is a synergistic effect among the three drugs.

Senator HUMPHREY. Well, that would help considerably, even if it doesn't apply to every product, if you found that some of these were new drugs under the double-entity standard, or whatever—I think that would help significantly if you can do that.

Mr. Hile, you seem to advocate giving FDA greater authority to access records of manufacturing firms. Does that also include distributing firms or is that just manufacturers?

Mr. HILE. Our principal focus is on manufacturing, but the statute extends to distributors as well.

Senator HUMPHREY. You have that access where prescription drugs are involved but not nonprescription drugs.

Mr. HILE. That is correct.

Senator HUMPHREY. And you advocate that authority?

Mr. HILE. It certainly would be one way that the Food and Drug Administration could be more aggressive in its inspectional activities of manufacturers. We cannot now investigate records to determine where raw materials are received, the number of batches that are made, where they are distributed, and that sort of thing, for over-the-counter drugs.

Senator HUMPHREY. Why haven't we done this before? Has it been advocated previously?

Mr. HILE. Well, in 1962, with the passage of the Kefauver amendment, the Congress did debate whether or not that authority should be extended to over-the-counter drugs, and concluded that it should not.

The concern over this kind of need is, of course, only relatively recent in relationship to the passage of the 1962 amendment.

Senator HUMPHREY. In any case, you would advocate extension of that authority to nonprescription on an ingredient basis, a selective basis?

Mr. HILE. I think that would be a reasonable approach, narrowly drawn would not impose an undue regulatory burden on the entire over-the-counter drug industry.

Senator HUMPHREY. Well, that industry is backing us, at least in general terms, and we want to keep them on our side, so we don't want to unduly interfere with their business.

You also advocate injunction authority to prohibit manufacturers from continuing activities. You can seize lots of drugs, but you don't have the authority to enjoin further activity, and you advocate that.

Mr. HILE. Yes, that is an anomaly that applies only to counterfeit drugs, and I think was a legislative oversight, and that certainly would be something that could be taken care of in any new legislative initiative.

Senator HUMPHREY. Legislative oversight—I didn't know we had any of those.

This question is akin to another I asked, but has the FDA consider placing the caffeine-ephedrine combinations into the schedule of controlled substances?

Mr. HILE. The Controlled Substances Act sets forth some several tests—I will characterize them as tests, or requirements—that are necessary to consider before a drug can be considered for scheduling. Furthermore, the Controlled Substances Act focuses strictly on a drug entity.

So our first concern is whether or not we can pass the current threshhold requirements to determine whether one or all of these active ingredients could be a scheduled drug; and, second, we have to think through very carefully what it would mean to put any one of them, say, as an example, caffeine, which is a widely used drug ingredient, and safely used in many, many drugs for legitimate

purposes—if you put caffeine, make it a controlled substance, then it embraces all of the drugs that contain that substance.

And that is something that poses a dilemma for both DEA and FDA in considering whether or not the current CSA and scheduling structure is a reasonable way to control these drugs.

Senator HUMPHREY. Let me direct a few questions to Ms. Pedersen.

You remark in your statement, page 3, "There is no change that can be made in the advertisements for look-alike drugs to render them acceptable."

What has the FTC done, then, if that is the finding that the advertisements are unacceptable—what has the FTC done?

Ms. PEDERSEN. Could I make one clarification regarding the status of my testimony before I answer your question?

Senator HUMPHREY. Yes.

Ms. PEDERSEN. I would like to make clear that, under Commission procedures, even where testimony represents my views, the Commission unanimously has authorized that I appear and delivers this testimony.

Senator HUMPHREY. The FTC was unanimous in this?

Ms. PEDERSEN. The Commission was unanimous in authorizing this presentation.

Senator HUMPHREY. That's the first time they have been unanimous on anything in a while, isn't it? OK, thank you for that clarification.

Ms. PEDERSEN. In terms of the Commission authority over advertising, the FTC ordinarily gets involved in advertisements for legitimate products that may have a deceptive element, a failure to disclose something. If you read the paper this morning, you will see we issued two opinions yesterday, one against Sterling Drug and the other against Bristol-Myers.

Our advertising activities tend to involve legitimately marketed products where there may be some problem in the ad.

Senator HUMPHREY. Legitimate products illegitimately advertised.

Ms. PEDERSEN. Yes, or there may be a failure to disclose.

With regard to look-alikes, there is no kind of advertising remedy. We can't say, if you disclose x properly in these ads, we will then find them acceptable. It is the advertising and marketing of these basically illegitimate products that is the core of this problem, and our usual remedies go toward fixing a problem in the competitive marketplace.

Senator HUMPHREY. Yes, you have no means of going after the marketing of illegitimate——

Ms. PEDERSEN. Well, our agency is designed to examine indepth complicated economic issues and really not to get out into the schoolyard where pushers are selling drugs to kids. We don't have that kind of investigatory resources.

Senator HUMPHREY. So the FTC at present has no ability to eliminate the ability of these manufacturers and distributors to advertise, is that correct?

Ms. PEDERSEN. We are prohibited by statute from using unfairness in advertising as a basis for rulemaking so we would have to proceed case by case. We would have to pursue one little company

after another. We are currently considering whether there is any effective remedy that we could, under our authority, implement in this area.

Senator HUMPHREY. You have had an investigation into this?

Ms. PEDERSEN. Yes, there was a staff proposal. It was made at the time when look-alikes were look-alikes. As you know, the industry has been relatively fast moving. This presents additional problems in terms of reassessing what useful role could we play in remedying this problem.

Senator HUMPHREY. When are there going to be findings, when will there be a report on this investigation?

Ms. PEDERSEN. The usual Commission practices don't culminate in a report on an investigation. Ordinarily the staff at a certain level can spend a 100 hours working at a problem; after that they have to come to the Bureau for approval. Often the Bureau will approve some portions of a recommendation and disapprove others. Investigations may culminate in a complaint recommendation against a company, a proposal for rulemaking, a proposal to institute voluntary industry education and compliance efforts or a closing of the investigation. The result will depend on the nature of the project, the problem as we see it, and our ability to take an effective action.

Senator HUMPHREY. Mr. Haislip, the administration had very considerable success with its model Imitation Controlled Substances Act in the States. Do you have any plans, since the mode of operation has shifted now to act-alikes really—do you have any plans to develop model legislation for the States that would help them in this regard?

Mr. HAISLIP. Well, this is a matter to which we are continuing to give attention. The difficulty, as I indicated in my summary, is separating this activity from what is otherwise legitimate-type activity. For example, I think that responsible industry in this country is equally appalled by this type of activity.

But from a legal point of view, we are talking about OTC preparations. These are preparations which are sold over the counter, generally through the mail.

So the problem becomes one of how to separate an undesirable element from the activity that is otherwise desirable and vital—indeed, most of us do purchase over-the-counter preparations of one kind or another at some time.

The possible approaches here, in view of the method that has been taken here, it seems to me that if we can't go against the product itself, which may be the case, if we cannot go against the double-entity or the particular products, which may be a difficulty, then we have to consider the mode of distribution or possible restrictions on the purchaser, possible age restrictions might be a consideration; a proof-of-age restriction, in fact, would probably make it impossible to obtain these through the mails, since there might be no way to prove age under such a statute.

Now, I am afraid that I have to say that I don't know if these ideas have merit; I am simply trying to reflect to you some of our further thinking and study, which we are not doing in isolation—we are doing that in consultation with those here and others as well.

I think the meetings we have had on this, we are all equally anxious to find final solutions to it, but it is a delicate piece of surgery. That is the best answer I can give you at the moment. We are continuing to look at this actively.

Senator HUMPHREY. In the area of setting up some kind of an age standard beyond the sale through the mail, how would you implement that in the case of private carriers and so on?

Mr. HAISLIP. Well, I think if——

Senator HUMPHREY. Just make it unlawful for someone—to require the seller to——

Mr. HAISLIP. If it's unlawful, if it's a criminal offense, I don't think you are going to find many people who are going to risk listing themselves in magazines or the yellow pages to be easily prosecuted.

Senator HUMPHREY. In other words, you would require some kind of—you would require the sellers to request some kind of proof of age or something? How would you do that through the mail?

Mr. HAISLIP. Well, I don't know.

Senator HUMPHREY. At long distances.

Mr. HAISLIP. It probably couldn't be done.

Senator HUMPHREY. Well, then, how would you do it?

Mr. HAISLIP. Well, maybe that's the object.

Senator HUMPHREY. I mean, what would you require of the sellers, that they establish age somehow?

Mr. HAISLIP. I understand the importance of your question, but my difficulty is that they go beyond where we stand in the analysis of the problem. I wish that were not the case, but it is.

The questions are important, but I don't have the answers.

Senator HUMPHREY. What about a model act to the States restricting sales to minors?

Mr. HAISLIP. This could have a good deal of merit. I think that needs to be explored. I think that we will be looking at that type of approach.

Senator HUMPHREY. All right, the proposal to restrict the quantities in any given sale——

Mr. HAISLIP. That might have merit as well. Many of these are sold in large quantities that never would be regarded as appropriate in any pharmacy or any legitimate activities as we know them.

Senator HUMPHREY. Does the FDA have authority to limit quantities of these kinds of drugs?

Mr. HAISLIP. We have never specified the size of a container or the number of units in a container that I can recall, Mr. Chairman, and that is something that we would have to explore, whether our authority would reach there or not.

Senator HUMPHREY. Senator Quayle.

Senator QUAYLE. Thank you very much, Mr. Chairman. First of all, I want to congratulate you on holding these hearings on an issue I think is important, and point out that I am one of your cosponsors, S. 503, the Imitation Controlled Substances Act.

I have a number of questions. I wasn't here for all of testimony and earlier questioning, so I apologize if my questions are repetitive. Has the panel agreed that this is a major national problem that the Congress should in fact deal with, Mr. Haislip?

Mr. HAISLIP. I think that you will have a number of different opinions on this, but I would like to give you mine. Because of the activities that the Federal Government has undertaken and the States in response to the Federal leadership, the look-alike problem appears to me to be rapidly declining—this is what our data shows.

Now there is a new problem, of marketing drugs that do not look like controlled substances. That problem seems to be growing. I believe it is a good deal smaller than the problem we have cured at this point; I am not sure where it is going to go. It has the indications of increasing.

Senator HUMPHREY. Thank you for yielding, Senator Quayle.

Dr. Cooper, would you give us your point of view on whether you think that the act-alike problem is smaller than the look-alike problem was?

Dr. COOPER. What I would like to do is answer the question you asked during my testimony, how do I account for the differences in perceptions.

I think that the easiest and best way to explain it is on methodological grounds. NIDA is measuring consumption directly among high school seniors. The DEA data is measuring indirect consumption through this particular technique of analyzing seizures.

Senator HUMPHREY. You are not in a position, then, to say that the new problem is less severe than the old one.

Dr. COOPER. What I can tell you was the data in 1982 showed an increase, and I gave you the prevalence figures. I also tell you that as recently as last month NIDA's community correspondents from Chicago and San Francisco are still reporting seeing the look-alikes as opposed to the act-alikes.

Senator HUMPHREY. Thank you.

Senator QUAYLE. Well, does the panel agree or disagree with what Mr. Haislip has said. If I could summarize the way that I interpret it, they thought that the look-alike was a problem, but has somewhat been resolved and now there is a new problem and you aren't exactly certain how it's going to come out. And therefore, I would detect that you would be telling us that this problem isn't a national interest or concern, or how big the problem really is and what we ought to be doing about it.

Mr. HAISLIP. If I could respond—that is so important, I think. I would hope that you would not interpret my remarks to mean that, because I don't suggest that.

First of all, it's very difficult to know what is going on in a nation of 220 million people with the data systems that we all possess. So this is a problem that we need to focus on and try to find solutions to.

I don't know the dimensions of it, and the evidence is that it is growing. We also have a good deal of field intelligence, because we have personnel stationed around the country. The information that we get from that source is, again, that the look-alike problem is definitely declining but what I have characterized as the so-called act-alike problem is beginning to take hold, and probably progressing.

But, as to the rate, the size and the relative proportions, I don't think that we know enough to be able to tell you that accurately.

Senator QUAYLE. Do you have enough vehicles in the way of enforcement and laws, et cetera, to counter this growing problem of the act-alikes?

Mr. HAISLIP. What we have been saying in various ways is that none of us here at this table or in the Federal Government have currently legal mechanisms designed to deal with this new problem, none of us. I think that is fair to say.

Senator QUAYLE. Well, then, if you have no legal mechanisms to deal with the problem, then you are going to need some legal mechanism, correct? Are you here today to urge us to get into the area of passing legislation which Congress does periodically? [Laughter.]

Mr. HAISLIP. We at least at DEA do not have for you a piece of legislation that we can recommend to deal with this problem because of the rapid changes that have occurred. It is a matter that we are continuing to review with our colleagues here. We don't have something to recommend to you. That doesn't mean that we are suggesting that Congress need not be concerned, because that is not the case.

Senator QUAYLE. I know the chairman of the subcommittee has done a lot to publicize the effects of drunk driving, alcoholism, and drug abuse and particularly the effect of each productivity. We haven't recommended any legislation in these areas, but we have had some rather significant substantive hearings which have informed the public about the problems. It is not always necessary to have legislation. That is why I am bringing the question up.

Now, I notice on page 11 of your testimony, you say, that the bill before you, that we are both sponsors of, is an attempt to deal with the problem, but in the view at DEA that this legislation is unlikely to succeed in dealing with major problems.

Now, what do you mean by that?

Mr. HAISLIP. Senator, that was an earlier draft.

Senator QUAYLE. Do you now endorse S. 503?

Mr. HAISLIP. Do I support it?

Senator QUAYLE. Yes.

Mr. HAISLIP. We see considerable problems with it. I think it would be difficult to answer all of the problems, but perhaps something of that kind needs to be pursued. And that was the reason why I eliminated that statement.

Senator QUAYLE. So this earlier draft we ought to drop that particular statement. Well, that's OK—that's deleted, and the record will show that.

So you are saying that S. 503, then, is going to be supported by you or what? You are going to make a recommendation to change it, should we proceed to try to enact something like that? I mean, we need to know what's going on in your department.

Mr. HAISLIP. Now that you are asking my opinion—and it is not a case of my volunteering an opinion—I would say that there are major legal problems with the approach in that bill, and that the bill probably would not reach some of the problems. There may be other ways that could be pursued.

But I think the bill is a forthright effort to deal with it, and it is certainly commendable in that regard.

Senator QUAYLE. Let me ask quickly a yes-or-no response from the other panel members: do we need legislation to deal with this new problem of act-alikes, Mr. Hile?

Mr. HILE. We have seen in FDA the possibility of additional legislation to strengthen our ability to regulate this particular phenomenon.

Senator QUAYLE. So you are saying yes, that you do need legislation?

Mr. HILE. Yes.

Senator QUAYLE. And has FDA recommended any legislation?

Mr. HILE. No, the agency is still working with the Department to consider whether or not and what kind of legislative proposal to——

Senator QUAYLE. Do you have any idea when that recommendation may be coming forward?

Mr. HILE. I'm sorry, I don't.

Senator QUAYLE. Six months, a year?

Mr. HILE. I can't——

Senator QUAYLE. Is this a priority within the agency? Do you see this as a growing problem?

Mr. HILE. I don't know whether it's growing or not, Senator. That is one of the problems. In other areas of drug abuse, the kinds of drugs that have been subject to that abuse have been around for a long time, and our concern over them has been over a long time, and we have a good data base to draw conclusions about whether or not the problem is growing or diminishing or remaining the same.

This is a reasonably recent phenomenon, and we really don't have the kind of data, at least from my standpoint, that would allow us to make really good solid—draw really good solid conclusions as to whether or not it was growing, diminishing, or remaining the same.

I would hope that the actions of the Food and Drug Administration over the last 2 years have had a positive impact and that the problem is diminishing. But I have nothing of my own in hand to confirm this.

Senator QUAYLE. Ms. Pedersen, is this a growing problem, and, if so, do you think you need a legal remedy?

Ms. PEDERSEN. Well, as my testimony indicates, we do see the need for some Federal legislation. I want to make clear, though, that the Federal Trade Commission does not have sort of data gathering capacity to allow us to assess independently the nature of this problem in terms of its volume.

From our discussions with the other agencies and our understanding that this problem seems to fall between the cracks in the various agencies' jurisdictions——

Senator QUAYLE. You don't collect that data—who does?

Ms. PEDERSEN. I assume some of it comes from NIDA and obviously DEA picks up——

Senator QUAYLE. Dr. Cooper, do you have that data and can you perhaps shed more light whether this issue is a major problem of growing proportions?

Dr. COOPER. Yes, I can. In my testimony previously, I indicated that although we started out with drugs that appeared one way,

the scene has evolved in that they now appear another way. The important part here is they still have same ingredients, either one or a combination of three or four different ingredients. The intent to distribute is the same. Likewise, the risk and the potential for consequences is the same.

From the available data we know that prevalence and trends are decreasing in a lot of areas of drug abuse, with several exceptions. One exception is this class of stimulants. There is evidence now to suggest that this class of stimulants is growing.

Senator QUAYLE. Mr. Nelson, can you contribute anything to the question I have been raising, whether or not it is a problem?

Mr. NELSON. Well, I represent the USPS, of course, and I would have to just base my answer upon Dr. Cooper's testimony and Mr. Haislip's testimony. If it is actually a growing problem, I think some legislation needs to be enacted to address it.

Senator QUAYLE. Who should be coming forth recommending legislation and what the legal remedy should be? DEA wants to volunteer for that.

Mr. HAISLIP. Senator, I think that all of us would have to be involved, and we indeed have met to discuss these issues as they have developed. I did want to mention, however, that——

Senator QUAYLE. You have got to have some main agency or individual in charge you know, these collegial bodies only work so well, and it's nice in theory, but, you know, somebody has got to make the decision, be responsible and accountable.

I would like to know who you think ought to be. Do you want to volunteer for that aqain? No. How about FDA?

Mr. HILE. Senator, I suspect logic would lead us all to conclude that the two agencies and the two departments that are most actively involved in the control of drugs that are abused, other than OTC look-alikes, are the Justice Department and DEA and the Department of Health and Human Services and FDA. If in fact you were going to identify anyone on this panel as having the primary responsibility for considering what kind of legislative solution would be appropriate, it would be those two, but I am not sure they could do it in isolation one from the other.

Senator QUAYLE. Does anybody anticipate that there is going to be some movement to come together to focus on this problem and to make a recommendation, or are we just going to try to further identify the problem?

What's your best "guesstimate," what within the administration and with your expertise in this area, what's going to happen, what should we expect?

Mr. HAISLIP. I know that you like definite answers.

Senator QUAYLE. I've been trying to get that for the last 10 minutes.

Mr. HAISLIP. But the reason is because of the complexity of the problem, and because of the fact that it is interwoven with legitimate activity. We have continued, as the problem changed, to meet and consult and try to develop plans to attack it—we are going to continue to do that. If we can find a legislative approach that will work, we are going to search for that. That is something we have been doing and we will continue to do.

I can't say that we will be able to find that in a particular timeframe.

There is also the possibility that we may be able to proceed through the model state approach, as we have previously. We obtained good results there. It may be that the problem can be dealt with to a large degree in that fashion and we are going to look at that, too.

This change from the look-alikes to the act-alikes is a very recent change. We had previously predicated all of our thinking and our plans and legislative designs on the look-alikes problem. That has changed. We have to focus on where it's gone.

And that is why we can't give you that definite answer that I understand you want.

Senator QUAYLE. So you are really telling us that you don't know enough right now to make that specific recommendation.

Mr. HAISLIP. That's correct.

Senator QUAYLE. Does the rest of the panel agree with that?

Ms. PEDERSEN. Senator, if I might, the Federal Trade Commission, while it is certainly not in my view the appropriate agency to be a drug enforcement agency, would have, I think, a useful role to play in terms of evaluating legislative efforts. This two-ingredient combination touches closely on legitimate drugs particularly generics. We at the Commission are more than willing to provide whatever expert assistance we have, from the antitrust and consumers protection points of view, to this effort.

But I really would say that we would not be an appropriate agency to take on this what I see as in essence a drug abuse regulation.

Senator QUAYLE. Well, I suppose the enforcement would either be at DEA or FDA, I would presume. Would that be a wrong presumption?

Mr. HILE. Well, Senator, in my testimony——

Senator QUAYLE. You decided you didn't want it—I gathered at that.

Mr. HILE. Well, we were in that business one time, Senator.

Senator QUAYLE. It didn't work very well?

Mr. HILE. We didn't do it very well.

Senator QUAYLE. Who should do it, who should be the enforcer?

Mr. HILE. Well, I am not certain that I am in a position to make that conclusion. But let me just expand a little bit.

Senator QUAYLE. How about giving us a hypothetical, hypothetically who do you think should do it? What is your best estimate on who should do it?

Mr. HILE. Well, let me just give you a brief bit of background, if I might.

Senator QUAYLE. Are you going to tell me who you think should enforce it?

Mr. HILE. I will tell you how it has been handled in the past.

Senator QUAYLE. I am not interested; I want to know who is going to enforce it now? Are you going to be able to answer that?

Who do you think, in your opinion—not official opinion of FDA—I mean, this is just your own opinion under onerous unfair questions from a Senator, to ask who ought to enforce the law that we are trying to create. I realize the unfairness of that question.

So I just ask your opinion, your personal opinion—Mr. Hile's personal opinion, and we might even go off the record, if you would like?

Mr. HILE. There is no need to do that.

Senator QUAYLE. OK. Who should enforce it?

Mr. HILE. My personal opinion is that if a Federal agency is to regulate the illegal sale of these products, that is, the street sale or a sale outside of the normal scheme of legitimate drug distribution, then there is only one agency that does that now, and that is DEA.

Senator QUAYLE. Thank you. Mr. Haislip, would you like to add anything to that? (Laughter.)

You can make it your personal opinion, too. Don't you think that you ought to enforce this?

Mr. HAISLIP. There are some problems with the statement that was made. First of all, the Federal Government doesn't enforce a drug law at the street level at all; that is a burden that the States and localities have. We have, as you know, about 2,000 investigators for the United States and the world.

But the problem here is that we are not concerned with sales outside of normal distribution; we are concerned with a distribution pattern that is occurring within the normal distribution. These people who are engaged in the undesirable activity are at the moment legal—that is the problem. These are drugs which at the moment can be sold to anyone at any age without a prescription. For example, under our law a prescription drug specifically cannot be controlled under DEA's laws, by statute.

So the problem here is different from street sales. That is asking the local police to clean up while we are licensing or approving people to manufacture and distribute these preparations for that purpose. That is taking the wrong end of the stick.

The problem is to regulate this kind of activity out of business through one means or another without, of course, affecting similar but legitimate activity. That is the problem. And it is certainly not the kind of operational problem that DEA is designed to deal with or has ever dealt with.

But it is a policy and as a matter of leadership issue because it affects the national drug problem, why, of course, we are certainly interested in that.

Senator QUAYLE. So you actually think the enforcement of S. 503 ought to be with FDA, the enforcement of this particular problem—that would be your opinion.

Mr. HAISLIP. Well, I have problems with S. 503 as being the exact approach that we need.

Senator QUAYLE. I understand that you may have some reservations about that, but I am talking about the enforcement of the law to get at the act-alike problem, and you seem to think that from right now, on this particular date, that FDA would be the proper agency to have enforcement powers?

Mr. HAISLIP. It seems to me that the legal matters are going to have to be determined around the availability of the product, age limitations, methods of distribution—these kinds of regulatory matters, which are——

Senator QUAYLE. Which are in the purview of FDA rather than DEA, that is what you are saying.

Mr. HAISLIP. Generally speaking, they have had concern over OTC products.

Senator QUAYLE. I see we have got a small problem just finding out who is going to enforce this.

I want to thank the chairman and also the panel. I would presume that since we are in the stage of data collection and trying to figure out whose role ought to be what that there will be further communication. I personally think that the chairman is right, that this is a problem, and is something I know affects the young people. And I would be hopeful that we might be able to work together and to try to get a little bit more definite position in the future. I have only just recently gotten into this issue—I have been here for about 45 minutes or 50 minutes—but I can see by the testimony that there is a huge haze out there covering what we really ought to be doing, and a lot of uncertainty. And we know there is a problem out there—we don't think anybody has disputed that there is a problem, that is the first question I asked. And I know the chairman is aware of it.

So when you have a problem, I think what we try to do is try to put the best talents on it and try to remedy the situation.

So I thank the chairman.

Senator HUMPHREY. Thank you, Senator Quayle, it is a thorny problem, one that is going to be difficult to get at, and the purpose of the hearing this morning is to elicit critique and suggestions, and I am sure that the participation and observations of the witnesses this morning will be instructive in that regard.

Thank you, each and everyone.

Our second panel is comprised of Representative Donna Sytek, chairman of the Judiciary Committee, New Hampshire House of Representatives; Dr. Arthur Maron, American Academy of Pediatrics; Mr. Gerald Baliles, Attorney General, Commonwealth of Virginia.

We welcome our second panel and thank them for their participation and their patience.

Our first witness is the Honorable Donna Sytek, member of the New Hampshire House of Representatives, chairman of the Committee on the Judiciary.

STATEMENT OF DONNA SYTEK, CHAIRMAN, JUDICIARY COMMITTEE, NEW HAMPSHIRE HOUSE OF REPRESENTATIVES; ARTHUR MARON, MEMBER, NATIONAL COMMITTEE ON DRUGS, AMERICAN ACADEMY OF PEDIATRICS; AND GERALD L. BALILES, ATTORNEY GENERAL, COMMONWEALTH OF VIRGINIA, A PANEL

Ms. SYTEK. Good morning, Mr. Chairman. It is interesting to be here this morning. I have a feeling of deja vu. We went through the same struggle that you are going through, identifying the problem, the extent of it, who is the appropriate agency to enforce, and exactly what is the right language to use.

I am here today primarily because I was the sponsor of House bill 54, an act to prohibit the sale of counterfeit drugs. This bill, which became law 2 weeks ago, grew out of the work of an interim study subcommittee which was formed to review our State drug

laws and to see if they were adequate to address New Hampshire's small but growing problem of drug abuse.

Testimony from State and local police quickly convinced us that there was a need to address the sudden surge of look-alike or turkey drug sales to teenagers. Students at the high school in my town told me that pills were being sold for $1 apiece in the schoolyard. Indeed, my local school board adopted a regulation to ban such sales on school property before the new law was enacted. And on the news the evening before I left to come down here. I notice the Bedford School Board enacted a similar ban. It is still a problem.

The State police showed us flyers and business cards distributed at concerts and in the mail promoting the sale of "legal" cocaine, black beauties, Christmas trees, purple hearts, bennies, and dexies—all street names for controlled drugs.

These are yellow jackets, these are black beauties, and here we have the whole array—we have robin's eggs, we have purple hearts.

Senator HUMPHREY. How recently were these confiscated?

Ms. SYTEK. These were seized last year in New Hampshire. These have all been submitted to our drug lab—these are all fakes. At one point, 40 percent of the specimens arriving at our forensic lab were found to contain no controlled substances; they contained the three elements that we are talking about this morning.

We found great reluctance on the part of the legislature to ban the sale of look-alikes because they contained only these three commonly found substances—caffeine, ephedrine, and phenylpropanolamine. As you heard this morning, these substances are commonly found in over-the-counter preparations and that they are safe when taken according to directions.

We also encountered resistance to prohibiting the sale of substances that happen to look like a controlled drug. After all, flour does have the same appearance as cocaine, and shouldn't we be happy that the teenager didn't buy the real thing? This is a very common argument: Where was the State interest in interfering in the sale?

It took a tragedy to put these arguments to rest. Over Christmas, a Littleton teenager died from an overdose of counterfeit purple hearts. The police chief from this small town in the White Mountains came to our hearing—I didn't even know that this had happened; he came out of the blue. But it was his testimony that turned my committee around. He told us that he knew who had sold the pills, the look-alikes, to this teenager, but because the pills contained no controlled drug, there wasn't anything he could do. And he urged us to enact a law to protect our young people. He brought out that youngsters often buy these turkey drugs and find that it takes four or five to get "high." The real danger comes when they unknowingly buy the genuine drug and take the same number of pills with life-threatening consequences.

In developing our State legislation, we had excellent cooperation from the State police, the pharmacy board, and lobbyists from the drug companies. We didn't have the interagency lack of cooperation that I see is apparent in Washington. We had an excellent working group.

Senator HUMPHREY. Let me just say in defense of the federal group, they are very busy with limited resources, which is really part of the problem; they are reluctant to take on new responsibilities.

Ms. SYTEK. We have had people voluntarily come forth from agencies and flood me with information and proposed solutions to the problem.

We considered many different approaches to the problem, from adding to the list of controlled substances the combination of caffeine and phenylpropanolamine, the so-called double- and triple-entity solutions. We even looked at expanding our fraud statute. All these attempts were found impractical because they just wouldn't work or they interfered with legitimate over-the-counter sales, the same problems that you are encountering here.

In our quest for the right language, we also examined several model acts, and we found them of questionable constitutionality. I know the DEA has one, the Proprietary Association has one—we looked at them all, and our lawyers told us we would be in court very fast if we enacted any of those.

The wording we finally settled on focuses on the representation made by the seller. Thus, if someone tells you the pill he is selling you is a black beauty, he would be in violation of the law, even if it were a fake. These were sold in the schoolyard as black beauties. We could charge them with a misdemeanor.

However, if he said: "These look like black beauties, and they are going to give you the same high, but they are legal," we could not find the magic words to do that, the words that would prohibit only that but not the sales of Dexatrim or things that people take for colds. We recognize the problem.

We settled on taking half a loaf. We will prohibit the sale of something represented as a controlled drug; that is an improvement in the law and we have got a lot of publicity on it. We think that that will have some impact, by no means solve the whole problem.

Your bill, Senator Humphrey, improves on our State law in that it doesn't rely only on the representation by the seller that the pill is a controlled drug, but it also focuses on the purported stimulant or depressant action of the substance. This would allow prosecution of those who push pills for "legal highs." I strongly support this as well as the section prohibiting the advertising of look-alikes.

In the research that you have done for this, I am sure that you have seen a lot of the advertising, but the one that made us so mad in New Hampshire was one that was received unsolicited in the mail, and I included it with my testimony. It was an ad for ephedrine speed, and the language that bothered us is the focus on the profit motive. It says:

> Somebody is making quite a profit, why not let it be you? You can sell these drugs by the hit and make $900 to $975 per bottle. But that would take too long. In the same amount of time, you could sell twenty bottles by the bottle, and net $2,000 or $3,000. Let your customers do the hard work.

And down further it says:

> Remember that you can sell them as speed. The law cannot do anything as long as you don't sell them as Amphetamine or as any other controlled substance.

You see, they are cashing in on the misery of our kids, and it was ads like that that got a lot of support for this type of legislation.

I do believe that there is a need for a Federal law in this area. Our pharmacy board has had, as recently as last month, inquiries from manufacturers as to whether New Hamphshire has a look-alike drug law. It would appear that the firms are shopping around for a place to do business and they will keep moving from State to State until something is done on the national level. So, if only for that reason, I think that there is need for Federal legislation.

I do think there is a national interest in protecting our kids from people who are out there to make a buck when their health is at stake.

These so-called recreational drugs are being marketed to unsophisticated children. They are dangerous and they provide an entry into the drug world. As a legislator and as the mother of a 13-year-old, I hope that your committee will act favorably on Senate bill 503 and stop the glamorization of the drug culture.

I would be happy to answer any questions.

[The prepared statement of Ms. Sytek follows:]

TESTIMONY OF NEW HAMPSHIRE STATE REPRESENTATIVE DONNA SYTEK
SUBCOMMITTEE ON ALCOHOLISM AND DRUG ABUSE
JULY 14, 1983

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE, MY NAME IS DONNA SYTEK AND I AM A FOURTH TERM MEMBER OF THE NEW HAMPSHIRE HOUSE AND CHAIRMAN OF THE HOUSE JUDICIARY COMMITTEE. DURING THIS LEGISLATIVE SESSION I SPONSORED HB 54, AN ACT TO PROHIBIT THE SALE OF COUNTERFEIT DRUGS. (SEE ATTACHMENT.)

THIS BILL (WHICH BECAME LAW TWO WEEKS AGO) GREW OUT OF THE WORK OF AN INTERIM STUDY SUBCOMMITTEE WHICH WAS FORMED TO REVIEW OUR STATE DRUG LAWS AND TO SEE IF THEY WERE ADEQUATE TO ADDRESS NEW HAMPSHIRE'S SMALL, BUT GROWING PROBLEM OF DRUG ABUSE.

TESTIMONY FROM STATE AND LOCAL POLICE QUICKLY CONVINCED US THAT THERE WAS A NEED TO ADDRESS THE SUDDEN SURGE OF LOOK-ALIKE OR TURKEY DRUG SALES TO TEENAGERS. STUDENTS AT THE HIGH SCHOOL IN MY TOWN TOLD ME THAT PILLS WERE BEING SOLD FOR $1.00 APIECE IN THE SCHOOLYARD. INDEED, MY LOCAL SCHOOL BOARD ADOPTED A REGULATION TO BAN SUCH SALES ON SCHOOL PROPERTY BEFORE THE NEW LAW WAS ENACTED. STATE POLICE SHOWED US FLYERS AND BUSINESS CARDS DISTRIBUTED AT CONCERTS AND IN THE MAIL PROMOTING THE SALE OF "LEGAL" COCAINE, BLACK BEAUTIES, CHRISTMAS TREES, PURPLE HEARTS, BENNIES, AND DEXIES--ALL STREET NAMES FOR CONTROLLED DRUGS.

THERE WAS GREAT RELUCTANCE, HOWEVER, ON THE PART OF SOME LEGISLATORS TO BAN THE SALE OF THESE LOOK-ALIKES BECAUSE THEY CONTAINED ONLY CAFFEINE, EPHEDRINE, AND PHENYLPROPANOLAMINE. THESE SUBSTANCES ARE COMMONLY FOUND IN OVER-THE-COUNTER DECONGESTANTS AND DIET PILLS AND ALLERGY MEDICATIONS, AND SAFE WHEN TAKEN ACCORDING TO DIRECTIONS. THERE WAS ALSO RESISTANCE TO

PROHIBITING THE SALE OF SUBSTANCES THAT HAPPEN TO LOOK LIKE A CONTROLLED DRUG. AFTER ALL, FLOUR DOES HAVE THE SAME APPEARANCE AS COCAINE, AND SHOULDN'T WE BE HAPPY THAT A TEENAGER DIDN'T BUY THE REAL THING?

IT TOOK A TRAGEDY TO PUT THESE ARGUMENTS TO REST. OVER CHRISTMAS, A LITTLETON TEENAGER DIED FROM AN OVERDOSE OF COUNTERFEIT PURPLE HEARTS. THE POLICE CHIEF FROM THIS SMALL TOWN IN THE WHITE MOUNTAINS TOLD US HE KNEW WHO HAD SOLD THEM TO HER, BUT BECAUSE THE PILLS CONTAINED NO CONTROLLED DRUG, THERE WAS NOTHING HE COULD DO. HE URGED US TO ENACT A LAW TO PROTECT OUR YOUNG PEOPLE.

BESIDES THE FACT THAT LOOK-ALIKES CAN KILL, IT WAS BROUGHT OUT THAT YOUNGSTERS OFTEN BUY TURKEY DRUGS AND FIND THAT IT TAKES FOUR OR FIVE PILLS TO GET "HIGH". THE REAL DANGER COMES WHEN THEY UNKNOWINGLY BUY THE GENUINE DRUG AND TAKE THE SAME NUMBER OF PILLS WITH LIFE-THREATENING CONSEQUENCES.

IN DEVELOPING OUR STATE LEGISLATION, WE WORKED CLOSELY WITH POLICE, THE PHARMACY BOARD, AND DRUG COMPANIES. WE CONSIDERED MANY DIFFERENT APPROACHES TO THE PROBLEM, FROM ADDING TO THE LIST OF CONTROLLED SUBSTANCES THE COMBINATION OF CAFFEINE AND PHENYLPROPANOLOMINE OR EPHEDRINE TO EXPANDING THE FRAUD STATUTE. ALL THESE ATTEMPTS WERE FOUND IMPRACTICAL BECAUSE THEY JUST WOULDN'T WORK OR BECAUSE THEY INTERFERED WITH LEGITIMATE OVER-THE-COUNTER SALES. IN OUR QUEST FOR THE RIGHT LANGUAGE, WE ALSO EXAMINED SEVERAL MODEL ACTS AND FOUND THEM OF QUESTIONABLE CONSTITUTIONALITY. THE WORDING WE FINALLY SETTLED ON FOCUSES ON THE REPRESENTATION MADE BY THE SELLER. THUS, IF SOMEONE TELLS YOU THE PILL HE IS SELLING IS A BLACK BEAUTY, HE WOULD BE IN VIOLATION OF THE LAW, EVEN IF IT WERE A FAKE. WE WERE UNABLE TO DEVELOP SATISFACTORY LANGUAGE THAT WOULD PROHIBIT SALES OF LOOK-ALIKES WHERE THE

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SELLER MAKES CLEAR THAT IT IS NOT REALLY A CONTROLLED DRUG.

SENATOR HUMPHREY'S BILL, S. 503, IMPROVES ON OUR STATE LAW IN THAT IT DOESN'T RELY ONLY ON THE REPRESENTATION BY THE SELLER THAT THE PILL IS A CONTROLLED DRUG, BUT ALSO FOCUSES ON THE PURPORTED STIMULANT OR DEPRESSANT ACTION OF THE SUBSTANCE. THIS WOULD ALLOW PROSECUTION OF THOSE WHO PUSH PILLS FOR "LEGAL HIGHS". I STRONGLY SUPPORT THIS AS WELL AS THE SECTION PROHIBITING THE ADVERTISING OF LOOK-ALIKES. (SEE ATTACHED FLYER FOR EPHEDRIVE SPEED.)

I BELIEVE THERE IS NEED FOR FEDERAL LAW IN THIS AREA. OUR PHARMACY BOARD HAD HAD INQUIRIES FROM MANUFACTURERS AS TO WHETHER NEW HAMPSHIRE HAS A LOOK-ALIKE DRUG LAW. IT WOULD APPEAR THAT THESE FIRMS ARE SHOPPING AROUND FOR A PLACE TO DO BUSINESS, AND THEY WILL KEEP MOVING FROM STATE TO STATE UNTIL SOMETHING IS DONE ON A NATIONAL LEVEL.

THESE SO-CALLED RECREATIONAL DRUGS ARE BEING MARKETED TO UNSOPHISTICATED CHILDREN. THEY ARE DANGEROUS. THEY PROVIDE AN ENTRY INTO THE DRUG WORLD. AS A LEGISLATOR AND AS THE MOTHER OF A 13-YEAR OLD, I URGE YOU TO ACT FAVORABLY ON S. 503 AND STOP THE GLAMORIZATION OF THE DRUG CULTURE.

9 Garrison Road
Salem, NH 03079

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Chapter 36

HB 54

STATE OF NEW HAMPSHIRE

In the year of Our Lord one thousand
nine hundred and eighty-three

AN ACT

to prohibit the sale of counterfeit drugs.

Be it Enacted by the Senate and House of Representatives in General Court convened:

36:1 Counterfeit Substances. Amend RSA 318-B:2 by inserting after paragraph I the following new paragraph:

I-a. It shall be unlawful for any person to manufacture, sell, purchase, transport or possess with intent to sell, dispense, compound, package or repackage (1) any substance which he represents to be a controlled drug, or (2) any preparation containing a substance which he represents to be a controlled drug, except as authorized in this chapter.

36:2 Affirmative Defense. Amend RSA 318-B by inserting after section 2-a the following new section:

318-B:2-b Counterfeit Drugs; Affirmative Defense. It is an affirmative defense to prosecution under RSA 318-B:2, I-a that the actor is:

I. A physician who sells, dispenses, or prescribes a substance which he represents to be or contain a controlled drug, but which in fact neither is nor contains a controlled drug to a patient under his care for a bona fide therapeutic purpose; or

II. A pharmacist who sells or dispenses a substance which he represents to be or contain a controlled drug, but which in fact neither is nor contains a controlled drug to a person at the direction of and upon the written prescription of an attending physician, provided any written prescription is properly executed, dated, and signed by the person prescribing on the day when issued and bears the full name and address of the patient for whom the drug is dispensed; or

III. A nurse or intern who, at the explicit direction of and under the supervision of an attending physician, administers a substance which he represents to be or contain a controlled drug, but which in fact neither is nor contains a controlled drug to a patient for a bona fide therapeutic purpose; or

IV. An emergency medical technician - paramedic who, upon receipt directly or by phone or by radio or by other communication medium of directions to do so from the supervising physician, administers a substance which he represents to be or to contain a controlled drug, but which in fact neither is nor contains a controlled drug to a patient for a bona fide therapeutic purpose.

36:3 Effective Date. This act shall take effect 60 days after its passage.

Approved: April 21, 1983
Effective date: June 20, 1983

EPHEDRINE SPEED

T.R. McWit Ephedrine Speed is real speed. One of the main ingredients in Ephedrine Speed is Ephedrine Sulfate. Ephedrine Sulfate is a legal stimulant that imitates Amphetamine. Ephedrine Sulfate is so similar to Amphetamine that another Ephedrine based drug called Desoxyephedrine HCl or Crystal Meth is classified as an Amphetamine under Schedule II of the Controlled Substance Act of 1970.

Amphetamine and Ephedrine Sulfate are both direct central nervous system stimulants. They both promote alertness and combat fatigue. They suppress the appetite effectively and relieve depression temporarily. All in all they give you energy which is what you need.

The current street value for a single hit of Ephedrine Speed, where they are consumed, is $1.00. The street value of a hit of Amphetamine is the same. A bottle (1000 hits) of Ephedrine Speed is $100.00 or 10¢ a hit. If large quantities are bought you can get as low as $25.00 a bottle or 2½¢ each. At a street value of $1,000.00 per bottle (when sold by single hits). Somebody is making quite a profit. Why not let it be you? We are not saying that you are going to net $900.00 to $975.00 per bottle. You should net profit $100.00 to $150.00 per bottle bringing the retail at your level of distribution to $250.00 to $125.00 depending on your market and quantity bought. Keep in mind that quantity is important to you and us. The more that is distributed the more is eaten. Sure you could sell them by the hit and make $900.00 to $975.00 net profit per bottle but it would take too long. In the same amount of time you could sell 20 bottles by the bottle and net $2,000.00 to $3,000.00. Let your customers do the hard work.

T.R. McWit Ephedrine Speed comes in 40 different capsules and tablets with different shapes and colors. Strengths vary too. Ephedrine Speed consists of a bitter confection of caffeine, Ephedrine Sulfate and Phenylpropanlamine HCl. We guarantee that our stimulants have more punch than caffeine.

Remember that you can sell them as speed. The law can not do anything as long as you don't sell them as Amphetamine or as any other controlled substance.

"VETERANS OF THE PILL BUSINESS"

T.R. McWit will meet any competitions price as long as you submit to us an ad or reciept of purchase that shows the stated price.

If you should need a certain stimulant that we don't carry in inventory, we will do our best to get it to you at regular T.R. McWit prices. Expect two weeks for final delivery of such merchandise.

Because of T.R. McWit buying power we may be able to sell you the same product that your present supplier offers you for a great deal less. Especially if his prices only make it feasible to buy in very large quantities when you only want a couple thousand of such product.

Contracts for large quantities over large or short periods of time are available to those persons who would like to get outragously low prices.

We are in business to serve you and the stimulants you need. Just give us a call if you have any questions or need a couple of tips. When calling use the regular number first. If no answer, then call the 24 hour service. Please leave your full name, address, telephone number and area code, plus exactly what you need. It will help if you will indicate the time you normally available at this number. If any probelm should arise in getting your order to you, we will contact you immediatly.

All orders will be shipped UPS Blue Lable C.O.D.. Cash only please. Expect 4 to 7 weekdays for delivery (4 weekdays if order is placed before noon).

Thank you for your time and cooperation. We hope this has been worth yours and our effort.

WELCOME TO T.R. McWIT

SAMPLES $5.00

QUANTITY	PRICE	TOTAL PRICE
100 - 900	$10.00 per 100	$10.00 - 90.00
1 bottle (1000)	$100.00	$100.00
5 bottles	$85.00	$425.00
10 bottles	$70.00	$700.00
25 bottles	$55.00	$1375.00
50 bottles	$40.00	$2000.00
100 or more bottles	$25.00	$2500.00 +

TELEPHONE: (305) 964-7102 24 HOUR SERVICE (305) 964-7209

ADDRESS: T. R. McWit
P. O. Box 6384
Lake Worth, Fla. 33461

Senator HUMPHREY. Thank you, Representative Sytek.

Mr. Baliles?

Mr. BALILES. Mr. Chairman, I am Gerald L. Baliles, attorney general of Virginia, and I appear before you today at your invitation and because of the growing concern of law enforcement and health-care professionals in our State over the use of combination drugs, comprised of nonprescriptive substances that are being marketed and used for nontherapeutic, recreational purposes.

In 1982, the Virginia General Assembly passed into law an Imitation Controlled Substances Act, which was designed to curb the sale and illicit distribution of so-called lookalike or counterfeit drugs.

The essential points of that law define imitation controlled substances as "a pill, capsule or tablet which is not a controlled substance, which by overall dosage unit, appearance, including color, shape, size, marking, and packaging or by representation made, would cause the likelihood that such a pill, capsule, or tablet will be mistaken for a controlled substance."

In addition, the act also makes a separate offense the advertisement or display for sale of imitation controlled substances.

Our research shows that there have been no prosecutions in the slightly more than 1 year that the law has been in effect in Virginia, and there is reason for that. Look-alike drugs are no longer the growing problem.

We are dealing with a very sophisticated industry which has changed over the years to stay just one step ahead of the law in developing substances for sale for nonmedical or recreational purposes.

Originally, these drugs closely resembled drug products containing substances regulated under the Federal Controlled Substances Act, but actually composed of combinations of substances available in an over-the-counter setting.

In the past several years, a number of States and the Federal Government, through the use of new and existing legislation and regulation, have brought legal action against the manufacturers and distributors of those look-alike counterfeits.

Following these legislative and enforcement actions, the traffickers in these drugs changed the physical appearance of their products so that they no longer fell clearly within the applicable State and Federal statutes.

Again, State and Federal agencies moved, this time to declare that the most prevalent of the over-the-counter combinations were new drugs, thereby prohibiting their continued distribution.

Following that declaration, the drug traffickers moved into a new generation of look-alike drugs, this time with a distinct appearance which does not mimic controlled drugs, and composed of combinations of substances not covered under the new-drug designation.

That is where we find ourselves today, with substances with little or no therapeutic value being marketed in publications, mailed material, billboards, and through word of mouth for solely nonmedical or recreational purposes, with the operations being generally inside present laws and regulations.

The result is predictable. In several Virginia cities, we find retail outlets for these combination drugs, where they are sold to young people as the real thing and for your stimulant needs. They are labeled as pink footballs, pink hearts, black mollies, and similar names, and sold in varying strengths at prices far above the market value for what is, in essence, a caffeine-ephedrine mixture.

The drugs quickly have found their way into the underground market, surfacing in school classrooms and video arcades, where they are sold to young experimenters who know little or nothing of the real dangers associated with such use.

Our regulatory and legislative efforts at the Federal, State, and local levels have been simply too slow and of too much a piecemeal effort to keep ahead of a rapidly mutating drug market.

The market is not a small one, nor is it limited to Virginia. Publications appear in nationally distributed drug-culture magazines. Flyers and printed material have appeared in a number of other States, including Texas and Arkansas, and some of that material has even included an advertising campaign designed to solicit schoolchildren at the third and fourth grade levels to act as agents for the sale and distribution of the combination look-alikes to their classmates.

We do not have completely accurate figures on the volume of sales of these combination drugs. We do know that the volume is high and there are indications from investigative sources that the profits are great. There may even be an informal franchising system to help protect exclusive markets for these retail operations.

In just one inventory of drugs at one store in Virginia, more than 1 million of the capsules and tablets were listed. A recent seizure for violation of drug repackaging regulations in a Virginia city resulted in the destruction of many thousands of dollars worth of the caffeine-ephedrine mixture.

Now, while it is impossible to draw totally accurate conclusions about the retail traffickers in these combination drugs, police investigative information provided my office indicates that individuals with criminal records are involved in various levels of the businesses. Those records show offenses ranging from assault, to possession of a concealed weapon, to drug violations, and the offenses have taken place in several States.

The health risk from the combinations can be substantial. Caffeine and ephedrine are central nervous system stimulants and they can act, in large quantities, much as controlled substance stimulants, such as amphetamines.

Let me just relate to you briefly information provided by a private drug-counseling agency in one Virginia city. A counselor relates that she has seen 500 to 600 junior high and high school students this year alone who are using these combination drugs either alone, or with alcohol, or with other legal and illegal drugs. About half that number were referred from school officials because of in-school drug use.

That figure is noteworthy, since the first retail outlet for these drugs did not open in that city until halfway through the school year. The children, as young as 12 years old, have often come to the school nurse, extremely agitated, with uncontrollable nervous-

ness, crying, depression, or manic behavior. They have told the nurse that they have worms or maggots crawling in their arms and they will not stop.

Now, those kinds of statements by young people in schools are literally frightening. They relate that they are deliberately taking these pills by the handfuls for the illicit effect they receive.

Illegal drug use is viewed in some levels of this youthful subculture as a rite of passage, and combination drugs are desirable because they are more easily obtained than marihuana, hashish, cocaine, or the opiates.

Now, that is an overview of the extent of the problem we have encountered. Let me turn briefly to enforcement efforts and the problems that we have discovered.

At the local level, there are few alternatives. Presuming that these retail outlets meet local zoning requirements, local authorities can do little to block the proliferation of these retail drug trafficking operations.

Police enforcement is aimed at collateral enforcement, in which drug paraphernalia laws are used when items such as marihuana clips or cocaine cutters are sold. The combination drugs are legal, so police have no edge in that area.

At the State regulatory level, we also find problems. If the drugs are repackaged in violation of pharmacy regulations, State officials can seize and destroy the product. But if the operators of drug businesses are careful to stay within the letter of State pharmacy packaging laws and regulations, our State enforcement efforts are limited.

My office, along with the State board of pharmacy and local officials, is reviewing legislation and administrative remedies for that problem. We expect to make certain recommendations to the General Assembly of Virginia in January 1984.

We now turn to the Federal spectrum. There are several possible legislative and administrative measures possible. We suggest that one effective enforcement method would be to use existing Food and Drug Administration authority to declare caffeine-ephedrine combinations as new drugs.

Under 21 U.S.C. section 35 355, the FDA must approve all drugs introduced into interstate commerce for safety and effectiveness. This approval authority extends to all new drugs entering interstate commerce. A new drug is any drug which is not generally recognized among qualified scientists as safe and effective for use under the conditions prescribed, recommended, or suggested.

Alternatively, a drug is a new drug if its safety and efficacy are proven in research "but which has not, otherwise than in such investigations, been used to a material extent or for a material time under the conditions suggested for use."

Under its authority to approve new drugs, the FDA may, after proper notice and under certain conditions, declare drugs discovered already to be in commerce as new drugs. Thus, drugs which are approved for one use may be declared new drugs for a different, unapproved use.

Such a declaration of new-drug status then requires the manufacturer to establish the safety and efficacy of the drug for this new purpose, and I refer you to the *Hoffman* v. *Sterling Drug* case

out of the third circuit a decade ago. Parenthetically, it would appear that the nonmedical, recreational marketing and use of caffeine-ephedrine would qualify in this area.

With respect to combination drugs, it must be demonstrated by the manufacturer that the combination of ingredients is safe and effective, even if individually the ingredients have been approved. And we refer you there, Mr. Chairman, to the district court case out of California 10 years ago. And a drug using the same combination of ingredients as an approved drug but in differing amounts is also a new drug requiring approval.

So, under its authority the FDA may declare certain combination drugs as new drugs for previously unapproved uses. This would require the manufacturers to prove safety and efficacy in the recommended use.

The FDA also has authority to declare drugs misbranded. Drugs may be considered misbranded if they do not contain adequate precautionary labeling to inform users of potential dangers. Under this authority, the FDA could require manufacturers of the drugs in question to place warnings on the labels.

There is a third potential solution, and this approach may in the long run, Mr. Chairman, have the most widespread impact. If the Federal Food and Drug Administration were to place the caffeine-ephedrine combinations into the schedule of controlled substances, those of us in law enforcement would then have the tools we need to strike out at the manufacture, marketing, distribution, and sale of combination drugs for nonmedical or recreational purposes.

Using authority already available to the agency, such a rescheduling, would give officials in the States where those drugs are manufactured additional authority to control the industry. Postal officials would be able to move more vigorously in controlling the unauthorized distribution of the drugs. And at the State level, we would have the weapons we need to force compliance with State and Federal controlled substance laws and regulations.

Such a scheduling would have little or no impact on the legitimate, over-the-counter industry since this combination is not used in any currently marketed product, from our research.

There is one final point I would make. The Food and Drug Administration has advised that the Federal regulations may prevent State regulators from adding to the State schedule of controlled substances a drug or combination of drugs not currently listed by Federal standards.

Regulatory reform to correct that oversight would also prove helpful to States facing this latest challenge to law enforcement.

Mr. Chairman, I have presented a generalized overview of the problem of over-the-counter combination drugs as we perceive it in Virginia. I do not believe our experiences or our enforcement problems are unique, however.

While we will continue our enforcement, regulatory, and legislative efforts in Richmond, I am convinced that we need the active and aggressive assistance of Federal authorities as well. I am equally convinced that we must move swiftly and effectively because the combination drug trafficking industry is moving aggressively.

One year ago, there were none of these retail outlets in Virginia. Today we know of more than a half dozen and the number is growing. The voice of Virginians is clear on this matter. They do not want these stores in their communities; they do not want these drugs in their schools, shopping malls, and in the hands of their children.

They are asking us for our help, and that help can come only if we can be effective in working together for a solution. Thank you.

[The prepared statement of Mr. Baliles follows:]

UNITED STATES SENATE

Subcommittee on Alcoholism and Drug Abuse

Senator Gordon Humphrey, Chairman

Testimony of

Gerald L. Baliles

Attorney General of Virginia

July 14, 1983

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(NOTE: Due to their voluminous content, and in the interest of economy, Tabs B, C, D, and E of Mr. Baliles' prepared statement were retained in the files of the committee where the material may be researched upon request.)

A

Mister Chairman, Members of the Subcommittee...I am Gerald L. Baliles, Attorney General of Virginia.

I appear before you today at the invitation of Senator Humphrey, and because of the growing concern of law enforcement and health care professionals in our State over the use of combination drugs, comprised of non-prescriptive substances, being marketed and used for non-therapeutic recreational purposes.

In 1982, the Virginia General Assembly passed into law an Imitation Controlled Substances Act, designed to curb the sale and illicit distribution of so-called look-alike or counterfeit drugs.

The essential points of that law define imitation controlled substances as "...a pill, capsule, or tablet which is not a controlled substance, which by overall dosage unit appearance, including color, shape, size, marking and packaging or by representation made, would cause the likelihood that such a pill, capsule or tablet will be mistaken for a controlled substance...." § 18.2-247.

In addition, the Act also makes a separate offense the advertisement or display for sale of imitation controlled substances. § 18.2-248.4.

OUR RESEARCH SHOWS THAT THERE HAVE BEEN NO PROSECUTIONS IN THE SLIGHTLY MORE THAN ONE YEAR THAT THE LAW HAS BEEN IN EFFECT IN VIRGINIA, AND THERE IS REASON FOR THAT. LOOK-ALIKE DRUGS ARE NO LONGER THE GROWING PROBLEM.

WE ARE DEALING WITH A VERY SOPHISTICATED INDUSTRY, WHICH HAS CHANGED OVER THE YEARS TO STAY JUST ONE STEP AHEAD OF THE STATE OF THE LAW IN DEVELOPING SUBSTANCES FOR SALE FOR NON-MEDICAL OR RECREATIONAL PURPOSES.

ORIGINALLY THESE DRUGS CLOSELY RESEMBLED DRUG PRODUCTS CONTAINING SUBSTANCES REGULATED UNDER THE FEDERAL CONTROLLED SUBSTANCES ACT, BUT ACTUALLY COMPOSED OF COMBINATIONS OF SUBSTANCES AVAILABLE IN AN OVER-THE-COUNTER SETTING.

IN THE PAST SEVERAL YEARS, A NUMBER OF STATES, AND THE FEDERAL GOVERNMENT, THROUGH THE USE OF NEW AND EXISTING LEGISLATION AND REGULATION, HAVE BROUGHT LEGAL ACTION AGAINST THE MANUFACTURERS AND DISTRIBUTORS OF THESE LOOK-ALIKE COUNTERFEITS.

FOLLOWING THESE LEGISLATIVE AND ENFORCEMENT ACTIONS, THE TRAFFICKERS IN THESE DRUGS CHANGED THE PHYSICAL APPEARANCE OF THEIR PRODUCTS SO THAT THEY NO LONGER FELL CLEARLY WITHIN THE APPLICABLE STATE AND FEDERAL STATUTES.

AGAIN, STATE AND FEDERAL AGENCIES MOVED, THIS TIME TO DECLARE THAT THE MOST PREVALENT OF THE OVER-THE-COUNTER COMBINATIONS WERE "NEW DRUGS," THEREBY PROHIBITING THEIR CONTINUED DISTRIBUTION.

FOLLOWING THAT DECLARATION, THE DRUG TRAFFICKERS MOVED INTO A NEW GENERATION OF LOOK-ALIKE DRUGS, THIS TIME WITH A DISTINCT APPEARANCE WHICH DOES NOT MIMIC CONTROLLED DRUGS, AND COMPOSED OF COMBINATIONS OF SUBSTANCES NOT COVERED UNDER THE NEW DRUG DESIGNATION.

THAT IS WHERE WE FIND OURSELVES TODAY, WITH SUBSTANCES WITH LITTLE OR NO THERAPEUTIC VALUE BEING MARKETED IN PUBLICATIONS, MAILED MATERIAL, BILLBOARDS AND THROUGH WORD OF MOUTH, FOR SOLELY NON-MEDICAL OR RECREATIONAL PURPOSES, WITH THE OPERATIONS BEING GENERALLY INSIDE PRESENT LAWS AND REGULATIONS.

THE RESULT IS PREDICTABLE.

IN SEVERAL VIRGINIA CITIES WE FIND RETAIL OUTLETS FOR THESE COMBINATION DRUGS, WHERE THEY ARE SOLD TO YOUNG PEOPLE AS "THE REAL THING," AND "FOR YOUR STIMULANT NEEDS." THEY ARE LABELED AS PINK FOOTBALLS, PINK HEARTS, BLACK MOLLIES, AND SIMILAR NAMES, AND SOLD IN VARYING STRENGTHS AT PRICES FAR ABOVE THE MARKET VALUE FOR WHAT IS IN ESSENCE A CAFFEINE-EPHEDRINE MIXTURE.

THE DRUGS QUICKLY HAVE FOUND THEIR WAY INTO THE UNDERGROUND MARKET, SURFACING IN SCHOOL CLASSROOMS AND VIDEO ARCADES, WHERE THEY ARE SOLD TO YOUNG EXPERIMENTERS WHO KNOW LITTLE OR NOTHING OF THE REAL DANGERS ASSOCIATED WITH SUCH USE.

OUR REGULATORY AND LEGISLATIVE EFFORTS AT THE FEDERAL, STATE AND LOCAL LEVELS HAVE BEEN SIMPLY TOO SLOW AND OF TOO MUCH A PIECEMEAL EFFORT TO KEEP AHEAD OF A RAPIDLY MUTATING DRUG MARKET.

THE MARKET IS NOT A SMALL ONE, NOR IS IT LIMITED TO VIRGINIA.

PUBLICATIONS APPEAR IN NATIONALLY DISTRIBUTED DRUG CULTURE MAGAZINES. FLYERS AND PRINTED MATERIAL HAVE APPEARED IN A NUMBER OF OTHER STATES, INCLUDING TEXAS AND ARKANSAS, AND SOME OF THAT MATERIAL HAS EVEN INCLUDED AN ADVERTISING CAMPAIGN DESIGNED TO SOLICIT SCHOOL CHILDREN AT THE THIRD AND FOURTH GRADE LEVELS TO ACT AS AGENTS FOR THE SALE AND DISTRIBUTION OF THE COMBINATION LOOK-ALIKES TO THEIR CLASSMATES.

WE DO NOT HAVE COMPLETELY ACCURATE FIGURES ON THE VOLUME OF SALES OF THESE COMBINATION DRUGS...WE <u>DO</u> KNOW THAT THE VOLUME IS HIGH, AND THERE ARE INDICATIONS FROM INVESTIGATIVE SOURCES THAT THE PROFITS ARE GREAT. THERE MAY EVEN BE AN

INFORMAL FRANCHISING SYSTEM TO HELP PROTECT EXCLUSIVE MARKETS FOR THESE RETAIL OPERATIONS.

IN JUST ONE INVENTORY OF DRUGS AT ONE STORE IN VIRGINIA, MORE THAN A MILLION OF THE CAPSULES AND TABLETS WERE LISTED.

A RECENT SEIZURE FOR VIOLATION OF DRUG REPACKAGING REGULATIONS IN A VIRGINIA CITY RESULTED IN THE DESTRUCTION OF MANY THOUSANDS OF DOLLARS WORTH OF THE CAFFEINE-EPHEDRINE MIXTURE.

WHILE IT IS IMPOSSIBLE TO DRAW TOTALLY ACCURATE CONCLUSIONS ABOUT THE RETAIL TRAFFICKERS IN THESE COMBINATION DRUGS, POLICE INVESTIGATIVE INFORMATION PROVIDED MY OFFICE INDICATES THAT INDIVIDUALS WITH CRIMINAL RECORDS ARE INVOLVED IN VARIOUS LEVELS OF THE BUSINESSES.

THOSE RECORDS SHOW OFFENSES RANGING FROM ASSAULT TO POSSESSION OF A CONCEALED WEAPON TO DRUG VIOLATIONS, AND THE OFFENSES HAVE TAKEN PLACE IN SEVERAL STATES.

THE HEALTH RISK FROM THE COMBINATIONS CAN BE SUBSTANTIAL. CAFFEINE AND EPHEDRINE ARE CENTRAL NERVOUS SYSTEM STIMULANTS, AND THEY CAN ACT IN LARGE QUANTITIES MUCH AS CONTROLLED SUBSTANCE STIMULANTS, SUCH AS AMPHETAMINES.

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LET ME JUST RELATE TO YOU BRIEFLY INFORMATION PROVIDED BY A PRIVATE DRUG COUNSELING AGENCY IN ONE VIRGINIA CITY.

A COUNSELOR RELATES THAT SHE HAS SEEN 500-600 JUNIOR HIGH AND HIGH SCHOOL STUDENTS THIS YEAR ALONE WHO ARE USING THESE COMBINATION DRUGS, EITHER ALONE, OR WITH ALCOHOL, OR WITH OTHER LEGAL AND ILLEGAL DRUGS. ABOUT HALF THAT NUMBER WERE REFERRED FROM SCHOOL OFFICIALS BECAUSE OF IN-SCHOOL DRUG USE.

THAT FIGURE IS NOTEWORTHY SINCE THE FIRST RETAIL OUTLET FOR THESE DRUGS DID NOT OPEN IN THAT CITY UNTIL HALFWAY THROUGH THE SCHOOL YEAR.

THE CHILDREN, AS YOUNG AS 12 YEARS OLD, HAVE OFTEN COME TO THE SCHOOL NURSE, EXTREMELY AGITATED, WITH UNCONTROLLABLE NERVOUSNESS, CRYING, DEPRESSION OR MANIC BEHAVIOR. THEY HAVE TOLD THE NURSE THAT THEY HAVE "WORMS OR MAGGOTS CRAWLING IN THEIR ARMS AND THEY WON'T STOP."

THE STATEMENTS BY THESE YOUNG PEOPLE ARE LITERALLY FRIGHTENING. THEY RELATE THAT THEY ARE DELIBERATELY TAKING THESE PILLS BY THE HANDFULS FOR THE ILLICIT EFFECT THEY RECEIVE.

ILLEGAL DRUG USE IS VIEWED IN SOME LEVELS OF THIS YOUTHFUL SUBCULTURE AS A RITE OF PASSAGE, AND COMBINATION DRUGS ARE DESIRABLE BECAUSE THEY ARE MORE EASILY OBTAINED THAN MARIJUANA, HASHISH, COCAINE, OR THE OPIATES.

THAT IS AN OVERVIEW OF THE EXTENT OF THE PROBLEM WE HAVE ENCOUNTERED. LET ME TURN BRIEFLY TO ENFORCEMENT EFFORTS AND THE PROBLEMS WE HAVE DISCOVERED.

AT THE LOCAL LEVEL, THERE ARE FEW ALTERNATIVES. PRESUMING THAT THESE RETAIL OUTLETS MEET LOCAL ZONING REQUIREMENTS, LOCAL AUTHORITIES CAN DO LITTLE TO BLOCK THE PROLIFERATION OF THESE RETAIL DRUG TRAFFICKING OPERATIONS.

POLICE ENFORCEMENT IS AIMED AT COLLATERAL ENFORCEMENT, IN WHICH DRUG PARAPHERNALIA LAWS ARE USED WHEN ITEMS SUCH AS MARIJUANA CLIPS OR COCAINE CUTTERS ARE SOLD. THE COMBINATION DRUGS ARE LEGAL, SO POLICE HAVE NO EDGE IN THAT AREA.

AT THE STATE REGULATORY LEVEL, WE ALSO FIND PROBLEMS. IF THE DRUGS ARE REPACKAGED IN VIOLATION OF PHARMACY REGULATIONS, STATE OFFICIALS CAN SEIZE AND DESTROY THE PRODUCT. BUT IF THE OPERATORS OF DRUG BUSINESSES ARE CAREFUL TO STAY WITHIN THE LETTER OF STATE PHARMACY PACKAGING LAWS AND REGULATIONS, OUR STATE ENFORCEMENT EFFORTS ARE LIMITED.

My Office, along with with the State Board of Pharmacy and local officials is reviewing legislation and administrative remedies for that problem. We expect to make certain recommendations to the General Assembly of Virginia in January, 1984.

We turn to the federal spectrum.

There are several possible legislative and administrative measures possible.

We suggest that one effective enforcement method would be to use existing Food and Drug Administration authority to declare caffeine-ephedrine combinations as "new drugs."

Under 21 U.S.C. § 35 355, the FDA must approve all drugs introduced into interstate commerce for safety and effectiveness.

This approval authority extends to all "new drugs" entering interstate commerce. A "new drug" is any drug which "is not generally recognized [among qualified scientists] as safe and effective for use under the conditions prescribed, recommended, or suggested." Alternatively, a drug is a "new drug" if its safety and efficacy are proven in research "but which has not, otherwise than in such investigations, been

USED TO A MATERIAL EXTENT OR FOR A MATERIAL TIME UNDER [THE] CONDITIONS [SUGGESTED FOR USE]." 21 U.S.C. § 321(P).

UNDER ITS AUTHORITY TO APPROVE "NEW DRUGS," THE FDA MAY, AFTER PROPER NOTICE AND UNDER CERTAIN CONDITIONS, DECLARE DRUGS DISCOVERED ALREADY TO BE IN COMMERCE AS "NEW DRUGS." THUS, DRUGS WHICH ARE APPROVED FOR ONE USE MAY BE DECLARED NEW DRUGS FOR A DIFFERENT, UNAPPROVED USE. SUCH A DECLARATION OF NEW DRUG STATUS THEN REQUIRES THE MANUFACTURER TO ESTABLISH THE SAFETY AND EFFICACY OF THE DRUG FOR THIS NEW PURPOSE. HOFFMAN V. STERLING DRUG, INC., 485 F.2D 132 (3D CIR. 1973). PARENTHETICALLY, IT WOULD APPEAR THAT THE NON-MEDICAL RECREATIONAL MARKETING AND USE OF CAFFEINE-EPHEDRINE WOULD QUALIFY IN THIS AREA.

WITH RESPECT TO "COMBINATION DRUGS," IT MUST BE DEMONSTRATED BY THE MANUFACTURER THAT THE COMBINATION OF INGREDIENTS IS SAFE AND EFFECTIVE, EVEN IF, INDIVIDUALLY, THE INGREDIENTS HAVE BEEN APPROVED. U.S. V. AN ARTICLE OF DRUG LABELED "ENTROL-C MEDICATED," 362 F.SUPP. 424 (D.C. CAL. 1973). AND, A DRUG USING THE SAME COMBINATION OF INGREDIENTS AS AN APPROVED DRUG BUT IN DIFFERING AMOUNTS IS ALSO A NEW DRUG REQUIRING APPROVAL. U.S. V. X-OTAG PLUS TABLETS, 441

UNDER ITS AUTHORITY, THEN, THE FDA MAY DECLARE CERTAIN COMBINATION DRUGS AS "NEW DRUGS" FOR PREVIOUSLY UNAPPROVED

USES. THIS WOULD REQUIRE THE MANUFACTURERS TO PROVE SAFETY AND EFFICACY IN THE RECOMMENDED USE.

THE FDA ALSO HAS AUTHORITY TO DECLARE DRUGS "MISBRANDED." 21 U.S.C. § 352. DRUGS MAY BE CONSIDERED MISBRANDED IF THEY DO NOT CONTAIN ADEQUATE PRECAUTIONARY LABELING TO INFORM USERS OF POTENTIAL DANGERS. UNDER THIS AUTHORITY, THE FDA COULD REQUIRE MANUFACTURERS OF THE DRUGS IN QUESTION TO PLACE WARNINGS ON THE LABELS.

THERE IS A THIRD POTENTIAL SOLUTION, AND THIS APPROACH MAY IN THE LONG RUN HAVE THE MOST WIDESPREAD IMPACT.

IF THE FEDERAL FOOD AND DRUG ADMINISTRATION WERE TO PLACE THE CAFFEINE-EPHEDRINE COMBINATIONS INTO THE SCHEDULE OF CONTROLLED SUBSTANCES, THOSE OF US IN LAW ENFORCEMENT WOULD THEN HAVE THE TOOLS WE NEED TO STRIKE OUT AT THE MANUFACTURE, MARKETING, DISTRIBUTION AND SALE OF COMBINATION DRUGS FOR NON-MEDICAL OR RECREATIONAL PURPOSES.

USING AUTHORITY ALREADY AVAILABLE TO THE AGENCY, SUCH A RESCHEDULING WOULD GIVE OFFICIALS IN THE STATES WHERE THOSE DRUGS ARE MANUFACTURED ADDITIONAL AUTHORITY TO CONTROL THE INDUSTRY.

POSTAL OFFICIALS WOULD BE ABLE TO MOVE MORE VIGOROUSLY IN CONTROLLING THE UNAUTHORIZED DISTRIBUTION OF THE DRUGS.

AND AT THE STATE LEVEL, WE WOULD HAVE THE WEAPONS WE NEED TO FORCE COMPLIANCE WITH STATE AND FEDERAL CONTROLLED SUBSTANCE LAWS AND REGULATIONS.

SUCH A SCHEDULING WOULD HAVE LITTLE OR NO IMPACT ON THE LEGITIMATE OVER THE COUNTER INDUSTRY, SINCE THIS COMBINATION IS NOT USED IN ANY CURRENTLY MARKETED PRODUCT.

THERE IS ONE FINAL POINT I WISH TO MAKE.

THE FOOD AND DRUG ADMINISTRATION HAS ADVISED THAT FEDERAL REGULATIONS MAY PREVENT STATE REGULATORS FROM ADDING TO THE STATE SCHEDULE OF CONTROLLED SUBSTANCES A DRUG OR COMBINATION OF DRUGS NOT CURRENTLY LISTED BY FEDERAL STANDARDS.

REGULATORY REFORM TO CORRECT THAT OVERSIGHT WOULD ALSO PROVE HELPFUL TO STATES FACING THIS LATEST CHALLENGE TO LAW ENFORCEMENT.

MISTER CHAIRMAN, I HAVE PRESENTED A GENERALIZED OVERVIEW OF THE PROBLEM OF OVER THE COUNTER COMBINATION DRUGS AS WE

PERCEIVE IT IN VIRGINIA. I DO NOT BELIEVE OUR EXPERIENCES OR OUR ENFORCEMENT PROBLEMS ARE UNIQUE.

WHILE WE WILL CONTINUE OUR ENFORCEMENT, REGULATORY, AND LEGISLATIVE EFFORTS IN RICHMOND, I AM CONVINCED THAT WE NEED THE ACTIVE AND AGGRESSIVE ASSISTANCE OF FEDERAL AUTHORITIES AS WELL.

I AM EQUALLY CONVINCED THAT WE MUST MOVE SWIFTLY AND EFFECTIVELY, BECAUSE THE COMBINATION DRUG TRAFFICKING INDUSTRY IS MOVING AGGRESSIVELY.

ONE YEAR AGO, THERE WERE NONE OF THOSE RETAIL OUTLETS IN VIRGINIA.

TODAY THERE ARE MORE THAN A HALF DOZEN.

THE VOICE OF VIRGINIANS IS CLEAR ON THIS MATTER, SENATOR. THEY DO NOT WANT THESE STORES IN THEIR COMMUNITIES; THEY DO NOT WANT THESE DRUGS IN THEIR SCHOOLS, SHOPPING MALLS, AND IN THE HANDS OF THEIR CHILDREN.

THEY ARE ASKING US, SENATOR, AS THEIR ELECTED REPRESENTATIVES, FOR HELP.

THAT HELP CAN ONLY COME, AND ONLY BE EFFECTIVE, IF WE WORK TOGETHER FOR A SOLUTION.

THANK YOU SENATOR HUMPHREY AND MEMBERS OF THIS SUBCOMMITTEE.

Senator HUMPHREY. Thank you, Mr. Baliles.

Dr. Maron?

Dr. MARON. Mr. Chairman, I am Dr. Arthur Maron. I practice pediatrics in West Orange, N.J. I am here today representing the American Academy of Pediatrics, which shares your concern with the growing problem of look-alike substances.

The academy wishes to commend you, Senator Humphrey, for recognizing the need to stop this drug abuse by introducing to this Congress S. 503 and S. 497.

The American Academy of Pediatrics believes this Nation should be made acutely aware that adolescents and young adults are abusing medication that has until now been regarded as sufficiently benign to be available without a prescription.

Obtained through legitimate over-the-counter channels or through the purchase of look-alikes on the street, and used in place of controlled substances, this medication can cause serious problems. When these drugs are taken with other substances such as alcohol, the serious potential risk is further accentuated.

Though regarded as sufficiently safe when taken as directed, abuse of drugs such as phenylpropanolamine can cause problems that may result in users needing attention in emergency rooms or physicians' offices. Here, and at poison control centers, look-alike capsule identification and content determination can be difficult, if not impossible, and even the patient does not always know what he or she has taken.

Conventional toxicological screening does not detect phenylpropanolamine, so the patient's symptoms and signs provide sometimes the only clue to what drug has been taken. In some doses, phenylpropanolamine frequently raises blood pressure to hypertensive levels and antidote and treatment measures in the emergency room are distinctly different for hard drugs and for look-alikes. Therefore, serious consequences are likely to occur when confusion exists.

Combinations of phenylpropanolamine and other over-the-counter medications have been noted to cause amphetamine-like reactions such as agitation, restlessness, irritability, sleep disturbance, tachypnea, tachycardia, hallucinations, manic episodes and psychotic reactions.

One adolescent and two young adult females who took similar preparations experienced chest pain, developed elevated creatine kinase levels, and showed electrocardiographic evidence of myocardial damage.

A 4-year-old and two adolescent females had seizures. One adolescent and a young adult male developed intracranial hemorrhages and died, and two other young adults had rhabdomyolysis and acute interstitial nephritis after taking phenylpropanolamine-containing preparations.

Senator HUMPHREY. Pardon me. What is rhabdomyolysis?

Dr. MARON. Muscle dissolution and edema in the muscle.

Combination of these preparations with other individually harmless drugs can also increase the possibility of adverse effect. In addition, those who use look-alikes regularly day use unusually high dosages to obtain the desired effect and experience a serious and

perhaps fatal overdose when they eventually buy the hard drug that has been imitated and previously counterfeited.

Look-alikes are also marketed in quantities of thousands or more, and buyers are therefore tempted to become pushers of their extra supplies for a quick profit.

The American Academy of Pediatrics is concerned also that the advertising and street promotion of look-alike drugs will help to convince an impressionable generation of children and young adults that taking drugs such as uppers or downers is socially acceptable, medically harmless, and safe.

With your two bills, S. 497 and S. 503, Congress is confronting a situation which needs to be addressed. The manufacturers and local vendors of look-alikes have previously been safe from the law. Many States have attempted to control this problem through legislation, as we have heard this morning, and this certainly is helping. However, this is a national problem which needs to be addressed to prevent it from growing and spreading further.

The American Academy of Pediatrics recognized this fact last year and developed informational packets and posters such as you see here this morning for use by our State chapters, of which we have 54. These State chapters have helped to pass State legislation and are more importantly educating the population at large to the dangers and ill effects of this drug abuse.

Legislation now existing in the States varies, however, in scope and enforcement. Dealing with the look-alike drug industry in this manner does not eliminate it completely because there are still areas of the country where it is legal.

Therefore, a Federal agency must become responsible and your bill designating the FDA as that agency is apparently appropriate. A nationwide law will control this lucrative area of the drug traffic.

Hence, we at the American Academy of Pediatrics enthusiastically support both these bills. As an organization of 25,000 pediatricians, the American Academy of Pediatrics has throughout its history strived to improve the health and condition of infants, children, adolescents, and young adults. Once again, we commend you, Senator Humphrey, for aiding us in this endeavor.

[The prepared statement of Dr. Maron follows:]

American Academy of Pediatrics

TESTIMONY

PRESENTED BY

ARTHUR MARON, M.D., F.A.A.P.

Mr. Chairman, I am Dr. Arthur Maron, a pediatrician from West Orange, New Jersey. I am here today representing the American Academy of Pediatrics where, as a member of its national Committee on Drugs, we have wrestled with the growing problem of look-alike substances. The Academy wishes to commend you, Senator Humphrey, for recognizing the need to stop this drug abuse by introducing to this Congress S. 503, the "Imitation Controlled Substances Act of 1983," and S. 497, which amends title 39 of the United States Code to prohibit advertising and shipping these drugs through the United States Postal Service.

The American Academy of Pediatrics believes this nation should be aware that adolescents and young adults are abusing medication that has until now been regarded as sufficiently benign to be available without prescription. Obtained through legitimate over-the-counter channels or through the purchase of "look-alikes," and used in place of controlled substances, this medication can cause problems. When these drugs are taken with other substances, such as alcohol, an even greater risk exists.

Legal highs, alternative energy sources and body stimulants are a few of the terms used commercially in advertisements to describe these dangerous substances. Not to be confused with legal generic drugs, look-alike substances are non-prescription drugs which resemble controlled drugs in shape, size, form and color and, on the street, are represented as controlled drugs. The manufacturer sells them in bulk as a "legal high" and the local vendor sells them as yellowjackets, black beauties, red devils, robin's eggs, and so on.

A decade ago tightening of drug laws restricted production and availability of popularly abused stimulant medications, setting the stage for increased use of non-prescription sympathomimetic drugs. Amyl nitrite was restricted to availability by prescription in 1969, and the Controlled Substance Act of 1972 may have reduced the manufacture of amphetamine 95 percent from the levels of the 1960's. In 1974, methaqualone, an hypnotic, was added to the list of substances covered by the 1972 Act. These changes, combined with the increased usage of cocaine during the 1970s fostered the production of these new "look-alikes."

Adolescents and young adults who abuse look-alikes locate sources of supply in several ways. Magazine advertisements that emphasize the "-amine" or "-caine" component of a drug and leaflets distributed at schools or other gathering places are two such ways. For their money they receive something which is more than a placebo, but not what they expect. Look-alikes can contain phenylpropanolamine, ephedrine, caffeine, lidocaine, or P,P'-Diaminophenylmethane or even a mixture of other substances -- most of which may be found in over-the-counter preparations marketed for the treatment of allergic symptoms, upper respiratory infections, obesity or for "pick-me-ups."

Though regarded as sufficiently benign to be available without prescription, phenylpropanolamine can cause problems and may result in users needing attention in emergency rooms or physicians' offices. Here, and at poison control centers, look-alikes capsule identification and content determination can be difficult and the patient does not always know what he/she has taken. Conventional toxicologic screening does not detect phenylpropanolamine, so the patient's symptoms and signs provide the best, or only, clues to the drug. In doses of 50-85mg., phenylpropanolamine frequently raises blood pressure to hypertensive levels[1].

Combinations of phenylpropanolamine and other over-the-counter medications have been noted to cause amphetamine-like reactions: agitation, restlessness, irritability, sleep disturbance, tachypnea, tachycardia, hallucinations, manic episodes, and psychotic reactions[2,3]. One adolescent and two young adult females who took similar preparations experienced chest pain, developed elevated creatine kinase levels, and showed electrocardiographic evidence of myocardial damage[4]. A four year-old and two adolescent females had seizures[3,5,6], one adolescent and a young adult male developed intracranial hemorrhages and died[6], and two other young adults had rhabdomyolysis and acute interstitial nephritis after taking phenylpropanolamine-containing preparations[7,8].

The formulation of the drug is of importance in producing complications: regular dosage forms are more likely to be toxic than timed-released preparations. Combinations of these preparations with other drugs can also increase the possibility of adverse effect[9]. In addition, those who use look-alikes regularly become accustomed to their effects and may experience a jolt when they actually take the drug that has been imitated or counterfeited. Look-alikes are usually sold in quantity and some buyers may be tempted to exchange their extra supplies for a quick profit.

With the introduction of your two bills, S. 497 and S. 503, Congress is confronting a situation which needs to be addressed. The manufacturers and local vendors of look-alikes have been safe from the law. Many states have attempted to control this problem through legislation and this is helping. However, this is a national problem which needs to be addressed to keep it from growing and spreading. The Academy recognized this fact last year and developed information packets and posters for use by our state chapters. The state chapters have helped to pass state legislation and are educating the population-at-large.

The legislation now existing in the states varies in scope and enforcement. Dealing with the look-alike drug industry in this manner does not eliminate it because there are still areas of the country where it is legal. It is vital that a federal agency become responsible and your bill designates the Food and Drug Administration as that agency. A nationwide law will control this lucrative area of the drug traffic.

Hence, we at the Academy enthusiastically support these bills. As an organization of 25,000 pediatricians the American Academy of Pediatrics has throughout its history strived to improve the health and condition of infants, children, adolescents and young adults. Once again, we commend you, Senator Humphrey, for aiding us in this endeavor.

Thank you.

Look-Alike Drugs. One Bite and it Could Be All Over

Dr. MARON. I might make one point briefly. There was some question before about the inability to limit quantities being sold from thousands down to a lower quantity. The American Academy of Pediatrics in past years has prevented a large number of deaths from aspirin by bringing the packaging of baby aspirin from thousands and hundreds to 24.

I am not sure which agency was responsible for this in the Federal Government, but I am sure one was and a similar situation could occur with this.

Senator HUMPHREY. Yes. That is an interesting insight. Thank you.

As you have heard from earlier testimony, there has been a shift away from principally look-alikes to act-alikes. But from the standpoint of the American Association of Pediatricians—is that it?

Dr. MARON. American Academy of Pediatrics.

Senator HUMPHREY. I beg your pardon; American Academy of Pediatrics.

From the standpoint of the academy, has there been any significant difference in health effects?

Dr. MARON. No. We are most concerned, whether they act alike or look alike, with the glamorization among the young people of taking drugs because it is safe and harmless, and it really is not safe and harmless. No matter what they look like, they are still terribly harmful.

Senator HUMPHREY. Yes. The ingredients are pretty much the same, irrespective of what their appearance might be.

Representative Sytek, have you begun to detect in your work a resurgence of the problem? As I understand the New Hampshire statute, it addresses counterfeit drugs; that is, look-alikes. Apparently, I assume the act-alikes are not controlled by that act; is that correct?

Ms. SYTEK. That is correct. The act-alikes were not such a problem as we did our research.

Senator HUMPHREY. Yes; I understand.

Ms. SYTEK. At that time, it was look-alikes, and so our whole focus was on that.

Senator HUMPHREY. Right.

Ms. SYTEK. At the forensic lab, there has been a decline in the number. It is still a problem. We are still finding look-alikes, but the advertising in the papers the kids read has changed from the look-alikes to the act-alikes.

It is an industry that responds very quickly to changes in the law and to changes in the marketplace.

Senator HUMPHREY. Yes; very clever.

Are we seeing in our State what apparently is happening in Virginia, the opening of retail outlets in our communities?

Ms. SYTEK. I have seen retail outlets for drug paraphernalia. I have not seen pills being distributed through stores. It is done through the mail.

Senator HUMPHREY. Are you giving thought to some further measure to close up this new loophole?

Ms. SYTEK. We have given a lot of thought to it, but we have the same problems with finding the magic words.

Senator HUMPHREY. Yes.

Ms. SYTEK. We are hoping that by having more people thinking about it and coming up with proposals—I have heard some this morning that we had not thought of in our little subcommittee, with all the help that we had.

We are hoping that by everybody concentrating on the problem, we can come up with a solution that does not interfere with legitimate sales. That has been the problem all along.

Senator HUMPHREY. Mr. Baliles, you suggested that the FDA use existing authority to declare caffeine-ephedrine combinations as new drugs. Also, elsewhere in your testimony you say that this combination is not currently used in any legitimate product. Have you researched that?

Mr. BALILES. Yes, sir, we have done it. Let me recommend, Senator, that you turn to tab B in our testimony. We have tried to provide for the benefit of the committee some background information. Have you found that, tab B?

Senator HUMPHREY. Yes.

Mr. BALILES. We have simply tried to point out there the background regarding PPA, caffeine, the ephedrine combinations, and the pharmacological properties of each one of those drugs, along with a brief analysis of the applicable State and Federal laws—criminal statutes, laws relating to pharmacies, and so on—along with a quick reference to cases, statutes and enforcement problems that we have encountered, thinking that it might be of some benefit to the committee.

I would mention to you that in tab B, that first section, originally after the imitation controlled substances laws were being passed, the look-alike statutes, the industry very quickly moved into that three-drug combination.

Senator HUMPHREY. Yes.

Mr. BALILES. FDA invoked its authority to declare a triple-combination drug a new drug. The industry simply dropped back and started using double combinations. We are simply saying if they have the authority to do for triple combination, they can do it for double combination.

Senator HUMPHREY. Yes. That is a very valuable finding because I thought it was implied earlier, although perhaps I am mistaken, that if they adopted this double entity standard, it would affect some legitimate over-the-counter products.

Mr. BALILES. In tab B, let me refer you to ephedrine. We point out there that that combination—you cannot get ephedrine sulfate without a prescription that is in excess of 25 milligrams. So, that figure remains constant in all of these pills and bottles that you will find. It will show reference to so many milligrams of caffeine; that is a variant.

But the ephedrine sulfate combination is always at 25 milligrams, and we point out in this material for you that you will find ephedrine used in certain over-the-counter drugs such as decongestant drugs. We mention some brand names there–Bronkotabs, Nyquil, and some of those.

You will not find, if you analyze those products, the ephedrine sulfate combination in combination with caffeine. We point out in our discussion on caffeine that it is a mild stimulant of the central nervous system. And on the basis of what we know, we have not

been able to find any over-the-counter drug that actually markets the drug in the combinations that we have been discussing here.

Senator HUMPHREY. Well, that is very interesting. We thank you for that research and we will include that submission, as well as all others offered by the witnesses, in the record.

Is the State of Virginia working on new legislation to address the act-alikes?

Mr. BALILES. Well, I indicated in my statement that we would be making certain recommendations to the 1984 general assembly. But we are somewhat concerned about FDA's statement to us that Federal regulations may preclude us from taking action on our own to include these combination drugs in a scheduled position in our law. I am not sure I agree with that legal analysis.

Senator HUMPHREY. Yes.

Mr. BALILES. But that is one indication I pointed out here that gives us some concern; whether we decide to abide by that or to rely on our own judgment in interpretation of the law remains to be seen.

Senator, could I volunteer one comment about terminology?

Senator HUMPHREY. Certainly.

Mr. BALILES. I served in the legislature in Virginia for 6 years and I am familiar with the legislative process, and I know that sometimes terminology is awfully important. It is common practice to refer to this problem as look-alikes, and I think there have been enough statements here today to indicate that we are not really talking about look-alike drugs.

So, if one goes to a legislative body that has passed a look-alike statute referring to a look-alike problem, which is really not look-alike by definition, I think you have an educational hurdle to overcome.

It seems to me we are talking about the dangers of combination drugs. It ought to be identified as such, and indicate by that use of terminology that you are dealing with a new generation of drugs.

If you look at your controlled drugs that have been placed in schedules by Federal and State laws, you are looking at controlled drugs that you cannot obtain except by prescription.

The problem came along when the drug industry said, "We will manufacture the imitations, the look-alikes, the counterfeits." So the laws were designed by terms to move against those drugs that were look-alikes of the controlled substances.

Senator HUMPHREY. Yes.

Mr. BALILES. Now they are not dealing with look-alikes; they are dealing with drugs that are hyped up. They are advertised as being something else. They do not fall within the legal framework of look-alike statutes, and by continuing to refer to them in those terms I think we create an educational problem.

Senator HUMPHREY. Your point is well taken, and I am uncomfortable myself about using a term that is no longer applicable for the reasons you cited. Perhaps we will try to adopt something new.

What do you think, Mr. Baliles, of the suggestions of our earlier panel of Federal witnesses that perhaps an alternative solution is restricting sales to minors? What effect do you think that would have?

Mr. BALILES. I did not hear all of the testimony, Senator, but what I did hear convinced me that that approach is looking at the wrong end of the problem.

Senator HUMPHREY. Yes.

Mr. BALILES. It is dealing with the problem after it is in the flow of market activity. It seems to me the most logical approach, the most effective alternative to take is to go at the source of the problem, the manufacturing end.

If those drugs are declared as new drugs in interstate commerce, they can be regulated at the point of manufacture and distribution.

Senator HUMPHREY. Right. What about the proposal to limit the number of capsules or pills for sale?

Mr. BALILES. Same answer. I think we are dealing at the receiving end.

Senator HUMPHREY. Yes.

Mr. BALILES. You can go into these retail outlets that are springing up in Virginia and you can get different sizes—big bottles, small bottles; a lot of drugs in one, not so many in the other. You can go up the street and buy another bottle, so I do not see where that really curbs the activity that we are concerned about.

Senator HUMPHREY. Well, very good. I thank each of you for your efforts and for coming here today and helping us.

Our third panel, and final panel, is comprised of Dolores Delaney, Virginia Beach, Va.; Mr. Marshall Hopkins, chief of police, Littleton, N.H.; and Mr. Jim Grant, principal, Temple School, Temple, N.H.

Ms. Delaney, I note that you are a member of the board of the National Federation of Parents for Drug-Free Youth. Are you representing that organization today?

STATEMENT OF DOLORES L. DELANEY, MEMBER OF THE BOARD, NATIONAL FEDERATION OF PARENTS FOR DRUG-FREE YOUTH, AND JUVENILE PROTECTION CHAIRMAN, VIRGINIA CONGRESS OF PARENTS AND TEACHERS; MARSHALL L. HOPKINS, CHIEF OF POLICE, LITTLETON, N.H.; AND C. JAMES GRANT, PRINCIPAL, TEMPLE ELEMENTARY SCHOOL, TEMPLE, N.H.; A PANEL

Ms. DELANEY. I would say that I speak for the National Federation, as well as the Virginia Congress of Parents and Teachers, a position which I also hold.

Senator HUMPHREY. Yes.

Ms. DELANEY. I have listened to the testimony all morning long, so if I might have your permission, there are places where in my oral testimony, if I might, I would like to respond to some of those things.

Senator HUMPHREY. Sure.

Ms. DELANEY. In 1980 in my city, when we first heard the term "look-alike," we presumed that they were talking about capsules which could be purchased empty and filled with the substance of choice. In that particular timeframe, we were seeing black capsules being sold as black beauties, which contained Sevin Dust, which is an insecticide, and/or, on occasion, dry bleach, such as Clorox II, which is fairly granular and might appear to an untrained eye to have properties similar to time-release capsules.

By the spring of 1981, of course, things began to change, and now we started getting the influx of advertisements about the look-alikes. In an October issue of People magazine, an article on this subject profiles a distributor in Lewistown, Pa. The gentleman was quoted as saying, "We feel bad about the cripples, but it is not our fault," and in that particular instance he was referring to young victims of strokes due to the use of these pills and capsules.

The postmaster of Lewistown was quoted as commenting, "I hear business will pick up here when school starts."

As a parent, I have to tell you that the fact that I would see that quote becomes offensive to me because we are talking about something where there is absolutely utter disregard for those purchasers of that product. And for those of us who have dealt for some time with this issue, we have to constantly remind ourselves that to everyone else in the world it is an economic issue.

In October of 1981, I drafted a resolution for the Virginia State PTA convention which called for legislation banning the manufacture, sale, distribution, possession and advertisement of look-alikes, and that resolution was unanimously adopted.

In the 1982 session of the Virginia General Assembly, four different bills were introduced dealing with this subject. I was requested to testify on that particular occasion by a member of the Virginia State Police. I was joined on that day by numbers of interested others, such as the nurses' association, pharmacists, principals, and teachers.

On that day in the hearing room of the House Courts of Justice Committee in Richmond, on dollies were boxes and cartons containing 1,600,000 dosage units of look-alike drugs seized from one very small town in Virginia—a very small town.

It bothered me somewhat in looking at two of these bills that the closing language stated, "It shall not be a defense to this act that the defendant believed he was purchasing a controlled substance." If you can imagine the time would come when we would have to write into law that a defendant could not use as a defense the plea that he thought he was acting illegally.

Our look-alike bill passed and was to go into effect July 1. In April prior to that, although the bill had already passed the general assembly, I received a call indicating a look-alike shop had opened in a small shopping center which was situated in a densely populated area roughly 1 mile from both an elementary and senior high school.

I contacted another parent and went to that store. I frequently do this when I am buying paraphernalia or other things because you rarely get a sales slip and you need a witness if you have to testify.

I showed the lady at the store a card which was like this [indicating], and I simply pointed to those items, not wishing to use the language myself, to see how these would be represented and how they were sold.

I asked for 15-day quantities, and she said, "You can get 'black beauty 127's', 'RJ-8's', 'Christmas trees,' 'robin's eggs,' 'hearts' and 'footballs.' " And when I pointed to this one particular tablet here, I said "What about this?" And she said, "the 'peaches' will not be in until Friday."

Those are all street terms for uppers, speed, amphetamines, or whatever you wish. I purchased them, and here is where I see replicated much of what I have seen today in testimony.

I contacted the area newspaper, the police, the FDA, and the leasing agent for the shopping center. The police said they could do nothing because the law was not in effect yet. The FDA said they would investigate. The leasing agent said he would have his attorney check about breaking the lease, and July 1 came and went and the store was still there until it moved to its present location.

Our commonwealth attorney said he could do nothing because the law contained no description as to what constituted a look-like, so we are in legal limbo land.

From the opening of that first store to today is a story of frustration, anger, resentment, and probably most of all, confusion. And I would just like for you to understand what we as parents have had to do because we could find no legal recourse, apparently.

We put economic pressure of a type that someone might understand on the shopping center leasing agent, moving them to attempt to evict this particular individual. He retained an attorney.

In the meantime, we appealed to the area military to declare it off limits to military personnel. And I might add parenthetically here that if we talk about military personnel, we are talking about people obviously over 17 and 18 years of age. I feel like age limit would have no effect whatsoever.

We finally ended up standing in silent vigil in the parking lot outside of the store with no placards or anything, simply as a deterrent to people who would not be so comfortable walking in under someone's watchful eye.

We continued doing that until the gentleman's behavior became so erratic that we could no longer be assured of our safety.

We are joined in these efforts by people in Norfolk and in Hampton and in Portsmouth, Va. What we have seen, Senator, is that the States cannot do this alone. I would willingly stand in parking lots forever if I thought that ultimately there was an end in sight. Human power simply is not going to solve this issue.

We have seen that for every action, there is an immediate reaction, and for every drug-related statute adopted by our States, there is an immediate response from this industry.

In responding to the subject of legitimate pharmaceutical companies, I have searched through the PDR for endless hours. I keep one by my phone because many times parents call trying to identify something they have found in their children's effects.

I simply cannot identify in the PDR any patent medication, over-the-counter preparation, which contains these drugs in combination. I informed our board of pharmacy of that.

While Bristol-Myers produces No-Doze, which contains 100 milligrams of caffeine, they also produce a hemorrhoid ointment suppository which contains 0.2 percent ephedrine sulfate. But nothing else in their formulary brings those two elements together.

That is why we have come to you and are delighted to see that your bills are here with us, because we frankly do not see that we can receive any type of redress in our State.

All of the arguments that have been presented here, we have heard. I have responded to the fact that they are sold in conven-

ience stores and supermarkets by the fact that I can find nowhere else where there are stores that sell only this particular type of medication.

In the response to the requirement for labeling, this label is one that I brought with me to indicate that they are very difficult to read. This particular product in this bottle contains 357 milligrams of caffeine and 25 milligrams of ephedrine sulfate. It is incidentally called a 357 magnum and it is bullet shaped.

There is nothing on this bottle or this labeling that tells me where this is manufactured. If I see something with an "A," with an "SKF," with an "MSD," with a script "L," I know those are Abbott; Smith, Klein, French; Merck, Sharpe, Dome; Lederle. If something happens with a child and I see that preparation, I have an emergency number I can call. To whom do we turn in the case of an overdose of these?

We have had a death in my city, and we have had a death by the most peculiar, circuitous route. A 12-year-old in our city was sold six pills that were portrayed to him as look-alikes because the media coverage has been that they are safe, they are no different than a cup of coffee.

He purchased the six pills for $6. He took the six pills and today he is dead because the six pills were not look-alikes, which he felt comfortable with, but they were indeed diazepam, or valium. So you have another subsidiary problem that no one knows what anyone is buying anymore.

Less than 18 months ago, there was one look-alike store in the Tidewater/Hampton Roads area. Today, there are five in that area alone, with an additional one opening soon. Three are owned by a 25-year-old entrepreneur who came to Virginia Beach last April as an unemployed worker from New York. He is now the owner and operator of at least three of these businesses and retains his own legal counsel.

The National PTA has as one of its priorities the screening of young people for high blood pressure. This is a problem of enormous proportions because there are numbers of undiagnosed hypertensive youth. Yet, here we have no control over these admittedly dangerous stimulants.

Interestingly, at a time when we are seeing on our shopping center shelves soft drinks that are now caffeine free, we have stores opening selling large amounts of caffeine. It insults the intelligence.

In closing, I would just like to say to you that we, the citizenry, feel that we have exhausted just about every remedy available to us. We have the overwhelming feeling that almost anyone involved in this industry has more rights than the average citizen.

We feel that the continuing proliferation of these look-alike shops presents a real and serious hazard to the public health, and we most strongly urge that you act on behalf of the hundreds of thousands of concerned citizens who appeal to you.

Senator Humphrey, the FDA has in the Code as one of its general directives the ability to declare something an imminent hazard to the public health. They can immediately cause it to be enjoined and they do not even have to have proof of how many deaths or

injuries might possibly occur. I would suggest that might be a viable thing for FDA to consider.

We are assured in the preamble to the Constitution that we are to act in pursuit of domestic tranquility, and yet there is no tranquility in our land at this time on this issue. In the Constitution, under the first amendment, which we all know, and I am sure applies to free enterprise and advertisement of these things, we might be reminded that Justice Holmes said that while the first amendment guarantees us many rights, it does not guarantee us the right to yell "fire" in a crowded theater.

I might say that he was probably referring to the ninth amendment because the enumeration in the Constitution does not deprive us of all other rights. So I would think that while, under the right of free enterprise, these businesses have a right to operate, they do not, of necessity, have the right to operate when they operate in a community or in an environment that the community as a whole finds is injurious. It would put the right of the individual over the collective right.

In a February 1980 issue of our local newspaper, an editorial decried the increasing use of mind-altering substances by our youth and concluded by saying that if it continued, in the future we would see a nation of drones. The closing line summarized by saying that a nation of drones would have had fools and knaves for founding fathers.

I do not want to be included in that group, nor I am sure do you or anyone else in a position of responsibility. Therefore, I would hope that we can begin to change this by acting.

Thank you very much.

[The prepared statement of Ms. Delaney follows:]

TESTIMONY

DOLORES L. DELANEY
VIRGINIA BEACH, VA

SENATE SUB-COMMITTEE ON ALCOHOLISM & DRUG ABUSE
JULY 14, 1983

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE, I AM DOLORES DELANEY, A RESIDENT OF VIRGINIA BEACH, VA. I AM A MEMBER OF THE BOARD OF THE NATIONAL FEDERATION OF PARENTS FOR DRUG-FREE YOUTH, THE VIRGINIA FEDERATION OF PARENTS, AND SERVE AS JUVENILE PROTECTION CHAIRMAN FOR THE VIRGINIA CONGRESS OF PARENTS AND TEACHERS (PTA). THESE ARE POSITIONS I HOLD AMONG OTHERS. HOWEVER, MY MOST IMPORTANT POSITION IS THAT OF MOTHER OF THREE SONS.

I AM HAPPY TO HAVE THIS OPPORTUNITY TO PARTICIPATE IN THESE HEARINGS FOR A VARIETY OF REASONS. FOR ONCE IN THE HISTORY OF THE BATTLE AGAINST THE USE OF MIND-ALTERING SUBSTANCES YOU HAVE AN OPPORTUNITY TO HALT SOMETHING BEFORE IT IS FIRMLY ENTRENCHED IN OUR SOCIETY.

I AM PARTICULARLY HEARTENED BY THE INTRODUCTION OF SENATE BILLS 497 AND 503, BOTH OF WHICH INDICATE AN UNDERSTANDING OF THE UNIQUE NATURE OF THE "LOOK-ALIKE" PHENOMENON WHICH HAS BECOME NATIONAL IN SCOPE.

IN 1980 WE FIRST BEGAN TO HEAR THE TERMS "LOOK-ALIKE" AND "PEASHOOTER," BUT IN MY PARTICULAR AREA WE HAD ASSUMED THIS REFERRED TO THE CAPSULES WHICH COULD BE PURCHASED EMPTY AND THEN FILLED WITH THE SUBSTANCE OF CHOICE. ADVERTISEMENTS OF THESE EMPTY CAPSULES WERE APPEARING IN NUMEROUS PUBLICATIONS AND COULD BE ORDERED BY MAIL. WE HAD INSTANCES WHERE THE BLACK CAPSULES SIMULATING "BLACK BEAUTIES" OR BIPHETAMINE ACTUALLY CONTAINED SEVIN DUST (AN INSECTICIDE) AND/OR DRY BLEACH WHICH WAS COARSE ENOUGH TO RESEMBLE SPANSULES FREQUENTLY SEEN IN TIME-RELEASE PREPARATIONS.

BY THE SPRING OF 1981, IT BECAME APPARENT THAT THERE WERE INDEED "LOOK-ALIKES" OF A DIFFERENT TYPE APPEARING. CARDS WERE IN EVIDENCE WITH COLOR PHOTOS OF A VARIETY OF PILLS AND CAPSULES REFERRING THE READER TO A POST OFFICE BOX. THEY WERE DESCRIBED AS "STIMULANTS AND SLEEP AIDS." IN MAGAZINES, ADVERTISEMENTS OFFERED A SEEMINGLY ENDLESS VARIETY OF CHOICES. COLLEGE STUDENTS WERE RECEIVING BROCHURES IN THE MAIL OFFERING DISCOUNT PRICES ON THESE DRUGS AND PARENTS WERE BEGINNING TO PROTEST.

IN AN OCTOBER ISSUE OF PEOPLE MAGAZINE, AN ARTICLE ON THIS SUBJECT PROFILED A DISTRIBUTOR IN LEWISTOWN, PENNSYLVANIA. THE GENTLEMAN WAS QUOTED AS SAYING "WE FEEL BAD ABOUT THE CRIPPLES, BUT IT'S NOT OUR FAULT," REFERRING TO YOUNG VICTIMS OF STROKES DUE TO THE USE OF THESE PILLS AND CAPSULES. THE POSTMASTER OF LEWISTOWN WAS QUOTED AS COMMENTING, "I HEAR BUSINESS WILL PICK UP HERE WHEN SCHOOL STARTS." A SAD COMMENTARY IN A NATIONAL MAGAZINE - AND STILL NOTHING HAS BEEN DONE.

IN OCTOBER OF 1981, I DRAFTED A RESOLUTION FOR THE VIRGINIA STATE PTA CONVENTION, REQUESTING LEGISLATION BANNING THE MANUFACTURE, SALE, DISTRIBUTION, POSSESSION AND ADVERTISEMENT OF "LOOK-ALIKES" WHICH WAS UNANIMOUSLY ADOPTED.

IN THE 1982 SESSION OF THE VIRGINIA GENERAL ASSEMBLY, FOUR DIFFERENT BILLS WERE INTRODUCED DEALING WITH THIS SUBJECT. I WAS REQUESTED TO TESTIFY ON BEHALF OF ONE OF THESE BILLS, JOINED BY THE NURSES ASSOCIATION, PHARMACISTS, PRINCIPALS, TEACHERS AND OTHERS INTERESTED. ON THAT DAY, IN THE HEARING ROOM OF THE HOUSE COURTS OF JUSTICE COMMITTEE, THERE SAT CARTONS AND CONTAINERS OF THESE PILLS AND CAPSULES IN THE AMOUNT OF 1,600,000 DOSAGE UNITS WHICH HAD BEEN SEIZED BY THE STATE POLICE IN THE SMALL TOWN OF WYTHEVILLE. IT IS AN INDICATION OF THE AURA WHICH SURROUNDS THE ENTIRE DRUG ISSUE THAT CLOSING LANGUAGE IN AT LEAST TWO OF THESE BILLS STATED "IT SHALL NOT

BE A DEFENSE TO THIS ACT THAT THE DEFENDANT BELIEVED HE WAS PURCHASING A CONTROLLED SUBSTANCE." IF YOU CAN IMAGINE THAT A TIME WOULD COME WHEN WE WOULD HAVE TO WRITE INTO LAW THAT A DEFENDANT COULD NOT USE AS A DEFENSE THE PLEA THAT HE THOUGHT HE WAS ACTING ILLEGALLY.

OUR "LOOK-ALIKE" BILL PASSED AND WAS TO GO INTO EFFECT JULY 1, 1982. IN APRIL I RECEIVED A CALL INDICATING A "LOOK-ALIKE" SHOP HAD OPENED IN A SMALL SHOPPING CENTER LOCATED IN A DENSELY POPULATED HOUSING AREA ROUGHLY ONE MILE FROM BOTH AN ELEMENTARY AND SENIOR HIGH SCHOOL. THE CIRCUMSTANCES SURROUNDING THAT ESTABLISHMENT ARE ATTACHMENT TWO.

I IMMEDIATELY CONTACTED ANOTHER PARENT AND WENT TO THE SITE. IT WAS NOON AND WE OBSERVED WHAT WERE OBVIOUSLY HIGH SCHOOL STUDENTS ENTERING THE STORE. I ENTERED, AND USING ONE OF THE CARDS CONTAINING COLOR PHOTOGRAPHS OF THE ITEMS FOR SALE, ASKED WHICH I COULD PURCHASE IN FIFTEEN-DAY SUPPLY QUANTITIES. I WAS TOLD THAT I COULD GET "BLACK BEAUTY 127s," "ROBINS EGGS," "CHRISTMAS TREES," "HEARTS," AND "FOOTBALLS." I POINTED TO ONE ITEM AND ASKED ABOUT THAT AND WAS TOLD THE "PEACHES" WOULD BE IN ON FRIDAY. THESE ARE ALL STREET TERMS FOR VARIOUS TYPES OF AMPHETAMINES AND STIMULANTS. I PURCHASED A SMALL QUANTITY OF EACH AND LEFT THE STORE.

I CONTACTED THE AREA NEWSPAPER, THE POLICE, THE FDA, AND THE LEASING AGENT FOR THE SHOPPING CENTER. THE POLICE SAID THEY COULD DO NOTHING - THE LAW WAS NOT IN EFFECT UNTIL JULY 1. THE FDA SAID THEY WOULD INVESTIGATE. THE LEASING AGENT SAID HE WOULD HAVE HIS ATTORNEYS CHECK TO SEE IF THE LEASE COULD BE BROKEN. JULY 1ST CAME AND WENT BUT THE BUSINESS STILL REMAINED, UNTIL MOVING TO ITS PRESENT LOCATION. WHEN QUESTIONED, OUR COMMONWEALTH ATTORNEY SAID HE COULD DO NOTHING BECAUSE THE LAW CONTAINED NO DESCRIPTION AS TO WHAT CONSTITUTED A "LOOK-ALIKE."

FROM THE OPENING OF THAT FIRST STORE TO TODAY IS A STORY OF FRUSTRATION, ANGER, RESENTMENT AND FINALLY, CONFUSION. HOW CAN IT BE THAT WE, AFTER ALL THIS WORK, STILL HAVE STORES SELLING OPENLY? HOW CAN IT BE THAT AFTER A PERIOD OF 17 MONTHS, INVESTIGATIONS, STATEMENTS BY NUMEROUS AUTHORITIES OUTLINING THE DANGERS OF THESE DRUGS, THE AGREEMENT BY ALL THAT THIS INDUSTRY SHOULD NOT BE ALLOWED TO CONTINUE TO FLOURISH, AND STILL WE SEE NO CHANGE?

WE HAVE STOOD IN SILENT VIGIL OUTSIDE THESE STORES TO DISCOURAGE YOUNGSTERS FROM ENTERING. WE HAVE PARTICIPATED IN COURT CASES ATTEMPTING TO EVICT THIS BUSINESS. WE HAVE APPEALED TO OUR ATTORNEY GENERAL, WHO, IN ALL THIS STANDS TALL BECAUSE OF HIS ATTENTION TO OUR INQUIRIES. AND NOW, FINALLY, WE ARE HERE BEFORE YOU, ASKING YOUR ASSISTANCE BECAUSE WE SEE THAT ULTIMATELY THE LEGISLATION MUST COME FROM WASHINGTON. IT IS NO LONGER POSSIBLE FOR US TO BELIEVE THAT ACTION WITHIN OUR STATES, ONE BY ONE, IS THE ANSWER.

WE HAVE SEEN THAT FOR EVERY ACTION THERE IS AN IMMEDIATE REACTION. FOR EVERY DRUG-RELATED STATUTE ADOPTED BY OUR STATES, THERE IS AN IMMEDIATE RESPONSE FROM THIS INDUSTRY. TODAY, FOR THE MOST PART, "LOOK-ALIKES" HAVE BEEN REPLACED BY THOSE ITEMS WHICH RESEMBLE NOTHING. SO FIRMLY IMBEDDED IN THE PSYCHE OF OUR YOUTH, IT HAS BECOME UNNECESSARY FOR THEM TO LOOK LIKE A CONTROLLED SUBSTANCE. IT IS ENOUGH THAT THEY ALTER YOUR PERCEPTIONS.

LESS THAN 18 MONTHS AGO THERE WAS ONE "LOOK-ALIKE" STORE IN THE TIDEWATER/HAMPTON ROADS AREA. TODAY, THERE ARE 5 WITH AN ADDITIONAL ONE OPENING SOON. THREE ARE OWNED BY THE 25-YEAR-OLD ENTREPENEUR WHO CAME TO VIRGINIA BEACH AS AN UNEMPLOYED WORKER FROM NEW YORK. TODAY, HE IS THE OWNER AND OPERATOR OF THREE BUSINESSES AND RETAINS HIS OWN LEGAL COUNSEL.

THE NATIONAL PTA HAS AS ONE OF ITS PRIORITIES THE SCREENING

OF OUR YOUNG PEOPLE FOR HIGH BLOOD PRESSURE. THIS IS A PROBLEM OF ENORMOUS PROPORTIONS BECAUSE THOUSANDS OF OUR YOUTH ARE UNDIAGNOSED HYPERTENSIVES. YET, WE HAVE NO CONTROL OVER THE SALE OF THESE ADMITTEDLY DANGEROUS STIMULANTS.

THE SAME WEEK THAT THE STORE IN VIRGINIA BEACH MOVED TO A NEW LOCATION, THEIR PRODUCT WAS IN THE HANDS OF ELEMENTARY SCHOOL CHILDREN OF OUR CITY. THE HORROR IS COMPOUNDED BY THE FACT THAT A 12 YEAR-OLD CHILD IN OUR CITY PURCHASED 6 PILLS SOLD TO HIM AS "LOOK-ALIKES" FOR ONE DOLLAR EACH. HE TOOK THEM - AFTER ALL, HE HAS HEARD THEY ARE NO WORSE THAN A CUP OF COFFEE -THAT CHILD IS DEAD TODAY. THE PILLS WERE VALIUM. PERHAPS THAT CHILD WOULD BE ALIVE HAD HE NOT SEEN WHAT APPEARED TO BE A PERFECTLY LEGITIMATE BUSINESS SELLING THESE PILLS UNHINDERED. PERHAPS HE WOULD NEVER HAVE TAKEN SUCH A DOSAGE HAD HE NOT BELIEVED HE WAS IN POSSESSION OF "LOOK-ALIKES." BUT, LET US CONSIDER FOR A MOMENT WHAT HE WOULD HAVE TAKEN IF THEY HAD BEEN SO-CALLED "LEGAL STIMULANTS." HE WOULD HAVE BEEN INGESTING A POTENTIAL DOSAGE OF 1950 MG. OF CAFFEINE IN COMBINATION WITH 150 MG. OF EPHEDRINE SULPHATE. USE OF MORE THAN 600 MG. OF CAFFEINE ALONE IN ONE DAY HAS BEEN REPORTED TO CAUSE SERIOUS SIDE EFFECTS. WE CAN ONLY IMAGINE WHAT THIS TREMENDOUS DOSAGE IN COMBINATION WOULD PRODUCE, BUT IT IS SAFE TO ASSUME THE CHILD WOULD HAVE SUFFERED THE SAME RESULT.

IN CLOSING, LET ME JUST SAY THAT WE HAVE EXHAUSTED JUST ABOUT EVERY REMEDY AVAILABLE TO US. WE HAVE THE OVERWHELMING FEELING THAT ALMOST ANYONE INVOLVED IN THIS INDUSTRY HAS MORE RIGHTS THAN THE AVERAGE CITIZEN. WE FEEL THAT THE CONTINUING PROLIFERATION OF THESE "LOOK-ALIKE" SHOPS PRESENTS A REAL AND SERIOUS HAZARD TO THE PUBLIC HEALTH, AND WE MOST STRONGLY URGE THAT YOU ACT ON BEHALF OF THE HUNDREDS OF THOUSANDS OF CONCERNED CITIZENS WHO APPEAL TO YOU.

WE ARE ASSURED IN THE PREAMBLE TO THE CONSTITUTION THAT WE ARE TO ACT IN PURSUIT OF "DOMESTIC TRANQUILITY." YET, THERE IS NO TRANQUILITY IN OUR LAND. WE ARE REMINDED IN THE NINTH AMENDMENT TO THE CONSTITUTION THAT "THE ENUMERATION IN THE CONSTITUTION OF CERTAIN RIGHTS, SHALL NOT BE CONSTRUED TO DENY OR DISPARAGE OTHERS RETAINED BY THE PEOPLE." WE FEEL THAT OUR RIGHTS HAVE BEEN ABRIDGED ON NUMEROUS OCCASIONS BECAUSE WE HAVE NO RIGHTS IN THE MATTER OF WHAT WE HOLD TO BE INJURIOUS OR DETRIMENTAL TO THE WELL-BEING OF OUR HOMES OR COMMUNITIES. WE FEEL THE RIGHTS OF OUR CHILDREN ARE BEING ABRIDGED BY THE CONTINUED ABILITY OF THE DRUG CULTURE TO ADVERTISE AND GLAMORIZE THEIR INDUSTRY DESPITE ITS AVOWED ILLEGALITY.

IN THE FEBRUARY 1980 ISSUE OF OUR LOCAL NEWSPAPER, AN EDITORIAL DECRIED THE INCREASING USE OF MIND-ALTERING SUBSTANCES BY OUR YOUTH AND CONCLUDED-BY SAYING THAT IF IT CONTINUED, IN THE FUTURE WE WOULD SEE A "NATION OF DRONES." THE CLOSING LINE SUMMARIZED BY SAYING THAT A "NATION OF DRONES WOULD HAVE HAD FOOLS AND KNAVES FOR FOUNDING FATHERS." I DO NOT WANT TO BE INCLUDED IN THAT GROUP NOR, I'M SURE, DO YOU. THEREFORE, LET US BEGIN TO CHANGE BY ACTING ON THE ISSUE BEFORE YOU LEST WE HAVE STILL ONE MORE INJURY TO THE NATIONAL CONSCIENCE.

ATTACHMENT #1 PEOPLE MAGAZINE ARTICLE

#2 BEACON ARTICLE

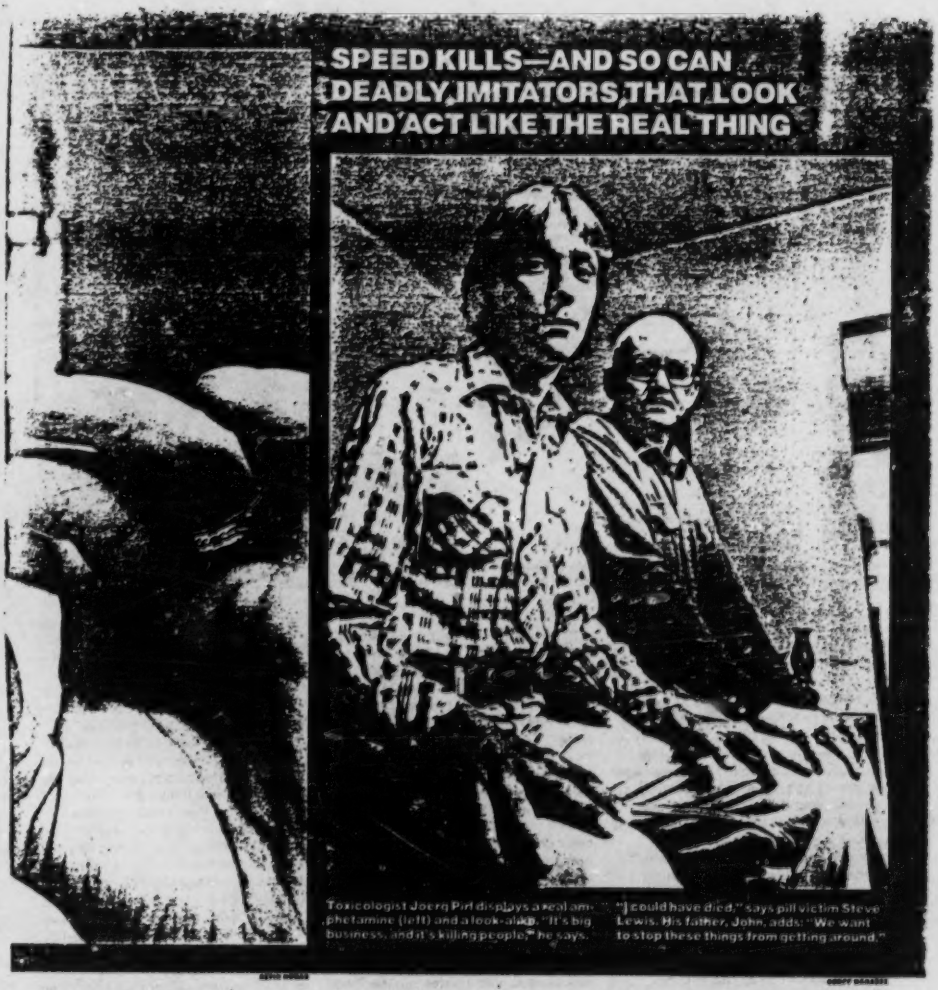
#3 VIRGINIAN-PILOT ARTICLE

#4 EXCERPTS FROM SUBCOMMITTEE ON CRIME, COMMITTEE ON JUDICIARY, HR

Like many 21-year-old rock guitarists, Steve Lewis nonchalantly shrugged off the dangers of drugs. He tried amphetamines and cocaine "once or twice on social occasions" and felt no ill effects. And he experienced only a mild high on each of the four or five occasions he dabbled in one of today's most popular drug fads—fake speed. The capsules, which look like amphetamines but derive their potent "rush" from caffeine and other legal stimulants, give users the kind of jittery high they might have if they gulped down 10 or 20 cups of coffee at once. So he didn't hesitate last Easter to pop three large yellow pseudo-amphetamines before a jam session with his mellow rock band in his hometown of Omak, Wash. Within minutes Lewis found himself terrifyingly close to death. "I got a headache, like one hell of a migraine," he recalls. "I remember I couldn't say anything. My whole right side was numb. I was scared. I don't remember anything about the next 48 hours, except for when my mom was at the hospital. It took me a week to realize what had happened."

Steve had suffered a massive cerebral hemorrhage—a stroke. When he regained consciousness, he could not speak. He could not see with his

SPEED KILLS—AND SO CAN DEADLY IMITATORS THAT LOOK AND ACT LIKE THE REAL THING



Toxicologist Joerg Pirl displays a real amphetamine (left) and a look-alike. "It's big business, and it's killing people," he says.

"I could have died," says pill victim Steve Lewis. His father, John, adds: "We want to stop these things from getting around."

right eye. His right side—his face, arm, hand and leg—was paralyzed. Six months later he has improved, but he still cannot play his guitar. "We came very close to losing him," his mother, Rosa Lee Lewis, says tearfully.

Lewis had become yet another victim of a new and largely legal form of drug abuse. As many as 12 deaths in the last two years have been linked to the growing menace known as look-alike drugs. The pills are manufactured by little-known firms and carry names like Dex, leading some users to confuse them with the powerful amphetamine Dexedrine. Other look-alikes are packaged in colored capsules to resemble street speed like "cadillacs" or "pink ladies." Since they are made mainly of caffeine, look-alikes are legal in all but 12 states and are advertised in drug-oriented magazines like *High Times*, read by many young people. Says one official in the Attorney General's office in Illinois: "Look-alikes are training wheels for the drug culture."

Illinois has traced four deaths to the drugs in the past seven months. State Attorney General Tyrone Fahner has sued 28 distributors of the drugs—10 of whom have agreed to stop doing business in the state—and introduced a bill to outlaw their manufacture and distri-

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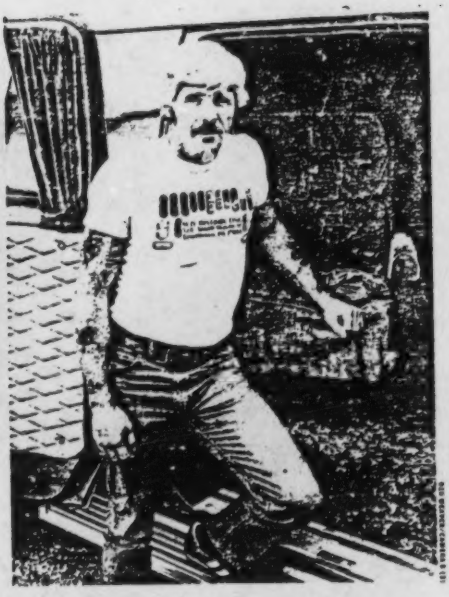
"I'm in the process of getting an accountant," boasts pill entrepreneur Dale Herto. "I'm in money that is out of my league."



Every day the Lewistown, Pa. post office handles shipments of thousands of look-speed pills to outlets around the country.

bution. "These drugs can be more of a problem than the hard stuff," he explains. "I'm trying to save lives."

As Illinois state toxicologist Joerg Piri explains, the 100 to 250 milligrams of caffeine in each capsule stimulate the heart and the central nervous system. The caffeine's effect is heightened by the addition of such other legal additives as ephedrine and phenylpropanolamine, commonly used in diet pills. A few look-alikes, Piri says, "could cause the heart to fibrillate—lose pumping action—and induce coma." Excessive consumption can simulate the symptoms of an amphetamine overdose, Piri's studies show, and a look-alike OD patient can die while doctors treat the wrong problem. "Since the drugs are not controlled, kids think, 'Hey, this can't do any harm to me,' " Piri observes.

Many of the drugs are mailed from post offices in and around tiny Lewistown, Pa., where over the past two years an estimated 130 businesses have sprung up to distribute them, taking advantage of the obscurity of a rural location. (Some are mom-and-pop operations that supplement the family income.) The caffeine and additives are obtained from chemical wholesalers. "We feel bad about the cripples, but it's not our fault," says Dale Herto, 32, owner of M.D. Distributing, one of Lewistown's larger look-alike retailers. Clifford Kerstetter, 38, a proprietor of Clifton Pharmacal Wholesale, which manufactures the pills, says: "I feel sorry for the people who have taken too many. Our whole culture abuses everything—beer, diet capsules, everything. But I can't do anything about that." Both men point out that every bottle they make has clear dosage instructions—but children buy loose pills from pushers, not drugstores.

Distributor Herto says that he will gross at least $300,000 this year and has a payroll of four, including his sister Pam. His most popular capsules cost him $12 per thousand and sell for $40. He claims to hold a patent on the R-902 pill, a capsule resembling street-sold "black beauties" amphetamines.

There are occupational hazards, of course. "We get letters from people threatening to break our legs, people who have had problems with their kids," says Herto. "When these people call, I apologize—if they allow me to." One Lewistown resident reportedly is paid $400 a week to start the cars at one drug company, as a precaution against bombs. Kerstetter keeps a kennel of guard dogs to protect his factory and home eight miles from Lewistown. "The people in this town are jealous," he says. "They see my cars and my house and they automatically think I must be doing something illegal."

Pennsylvania is in fact contemplating a law to ban sale of the look-alikes. Some major makers of empty drug capsules have announced that they will stop shipping their product to look-alike distributors. But the federal government has done nothing as yet, although the Food and Drug Administration is investigating. "Our legal department is trying to figure out what stand to take," says spokesman Christopher Smith, who adds that the Drug Enforcement Administration hasn't acted because "they're happy the kids are taking these rather than controlled substances." The U.S. Postal Service has also filed actions against 13 look-alike companies, accusing them of false advertising. Still, every afternoon a caravan of trucks from local pill distributors pulls up to the Lewistown post office, which mails out about 28,000 packages of look-alikes a year. Says Lewistown Postmaster Paul Bartholomew, sadly: "I hear business will pick up here when school starts."

CABLE NEUHAUS

Flood of 'lookalike' drugs feared

By BECKY BURCHER
Beacon Staff Writer

Drug abuse counselors in Virginia Beach fear entrepreneurs may be trying to saturate the city with bogus "lookalike" drugs before July 1 when a new law goes into effect banning the sale, manufacture and distribution of the imitations.

For uneducated consumers, the counselors say these pills may bring health problems such as high blood pressure and heart disease, or even death.

Under the law passed in this year's session of the Virginia General Assembly, it will be a misdemeanor to manufacture, sell, give or distribute the imitations and to possess them intending to sell or distribute them. Their advertisement for sale through handbills and displays will also constitute a misdemeanor.

(Continued on page 12)

Pills in hand

These are six pills which were sold at Beach Pharmaceutical. Local drug abuse counselors say they imitate amphetamines and 'common street speed,' but the vendor says they are no different from drugstore diet aids. Identified by the counselors and clockwise from the top, the pills look like Biphetamine, Ionamin, Histalet Forte, a street version of Benzedrine, a street version of speed called 'Footballs' and Fastin.

Beacon photos by David Hollingsworth

Beach Pharmaceutical in Thalia Shopping Center

Drug abuse counselors say 'lookalike' amphetamines are on sale here. 'Lookalikes' will be illegal in July when a new law banning their sale and distribution goes into effect.

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'Lookalike' drugs

(Continued from page 1)

Sale or distribution of imitations by adults to minors who are at least three years their junior will also be a felony.

Perry Ustick, director of the city's Comprehensive Substance Abuse Program, said he expects distributors of the fakes to make a "massive" effort to clear their warehouse shelves and put their products on the streets before they become illegal. Most of the previous imitation drug trade has been through out-of-state mail-order services, he said.

"They're just going to be pumping the Beach and Virginia with these things," he said.

Ustick and counselors who work for him say this has already occurred at one local business — Beach Pharmaceutical, a shop which opened in Thalia Shopping Center on April 1, about two weeks after the law was passed.

Beach Pharmaceutical, unlike a traditional pharmacy, deals exclusively in a diet pill and stimulant trade, the owner acknowledges. No prescriptions are filled there.

"What it is, is a storefront with a counter and boxes and boxes of these 'lookalike' drugs," Ustick said, speaking of Beach Pharmaceutical.

Beach Pharmaceutical so far is the only shop of its kind in Virginia Beach, Ustick said.

At the store, Ustick said, customers have bought pills and capsules of caffeine and other over-the-counter stimulants and decongestants which resemble prescription amphetamines. Two of the city's drug counselors say they have visited the new shop to inquire about its products.

(Continued on page 38)

Attachment #2 Va. Beach Beacon 5/82

Drug counselors fear flood of 'lookalike' pills

(Continued from page 12)

and the counselors have identified as "lookalike" drugs several pills bought at the store April 7.

But John Brewster, owner and manager at Beach Pharmaceutical, denies that he is selling "lookalikes" and says Uttick's theory that he is trying to unload stock before July 1 is wrong. In fact, he said, the new law will not even affect him.

"We're going to keep this completely legitimate," he said. "We have a legitimate business, and that's where we plan on keeping it. . . My wife and I found out if it was okay to run a business like this before we came.

"This is not a 'lookalike' business we're in. These are not 'lookalikes.' We discontinued those. We're not looking for no trouble."

The new law defines a bogus drug or an "imitation controlled substance" as "a pill, capsule or tablet which is not a controlled substance, which by overall dosage unit appearance, including color, shape, size, marking and packaging or by representations made, would cause the likelihood that such a pill, capsule, or tablet will be mistaken for a controlled substance."

Brewster said he did sell five types of capsules which were "lookalikes" when he first opened the Beach Pharamceutical, but later, upon learning that they were imitations of controlled drugs, he removed them from his stock.

Still, his business cards show color photographs of the capsules he says he no longer carries. "That's just a piece of paper with our number on it," he explained.

Inside Beach Pharmaceutical there are no sleek, flashy advertisements like those ordinarily found in a drug store. The only wall decoration is a hand-drawn poster announcing the special of the week, which Brewster said is typically his slowest-moving product.

The floor is bare cement and a single counter stretches the width of the shop. Beneath the counter Brewster stores some of his pills. On the counter are handbills and Brewster's full-color business cards.

Customers have no direct access to the merchandise. Two young women who shopped during a reporter's visit selected their purchases from Brewster's advertisements.

Brewster said there are other shops like his in Richmond and around the state, but he knows of no others like Beach Pharmaceutical in Virginia Beach.

Brewster said his products — which he gets in Long Island, N.Y. — are the same as over-the-counter stimulants found in grocery and drug stores. Beach Pharmaceutical's products are merely cheaper, he said. Primarily, his pills

Beach Pharmaceutical's card

It shows several 'lookalike' drugs, but the owner says he no longer carries the pills shown on the card

contain caffeine. Other common ingredients are the stimulants phenylpropanolamine and ephedrine.

Nevertheless, city drug counselors say there is danger in "lookalikes" which have been among Beach Pharmaceutical's products.

"There is a difference in the intensity and length of effect of a 'lookalike' and an amphetamine, and therein lies the danger," said Don Harris, supervisor of the city's drug abuse treatment program.

"Since they are 'lookalikes,' if someone were to obtain the real prescription, they could run into a problem."

For the teen-ager who takes three caffeine pills to achieve a rush and later takes three amphetamines believing they are the same pills, the results may be deadly, said Jeff Burns, a Virginia Beach drug counselor.

"The biggest danger," he said, "is that they look like a pharmaceutical product. There is no reason to make a caffeine pill look like an amphetamine except for appeal."

Burns said allergic reactions, hypertension and anxiety attacks are other dangers associated with imitation drugs. There are also added risks for those with heart disease and diabetes.

Beach Pharmaceutical's Brewster says he warns most of his customers of the dangers that may result from taking his products.

And, he said, he recommends that they take them only under a doctor's supervision. However, most of his customers tell him they do not want to consult a doctor, he said, because they are familiar with the pills and capsules they purchase.

Before coming from New York to Virginia Beach, Brewster said he operated a mail-order trade for the diet aids and stimulants. Now he is stocking seven or eight varieties of stimulants in Virginia Beach, he said.

A flyer Brewster distributes tells prospective customers that the store offers "a selection of body stimulants and generic diet aids designed to help you fight fat, fatigue and to help keep you mentally alert."

According to the flyer, a 15-day supply — 15 pills — costs $3. Brewster said he sells 1,000 tablets for $40 and 1,000 capsules for $50. In some mail-order businesses, 1,000 pills or capsules sell for as much as $125, he said.

"We're offering people what they want," he said. "They're not getting anything that's not on the bottle."

Brewster said he believes his business may eliminate the drug seller who sells a pill as an amphetamine when it isn't.

"We've got a place where kids can come out and find out exactly what they're getting," he said. "By kids I mean college kids."

A sign on the door says only those 18 and older are allowed inside. "That's our choice," Brewster said.

Del. Ted Morrison of Newport News, one of the legislators who heard countless hours of testimony on the imitation drug bill in the General Assembly, said there was much concern among parents, doctors, nurses and others over "the potential danger to health, particularly to young people."

"They brought in loads (of imitation drugs) by the thousands on dollies, tens of thousands," he said. "They just stacked them up all around the back of the committee room. It was just amazing. I didn't know there were that many pills in the world."

Morrison said the pills he saw had been confiscated by police who presumably believed they were amphetamines.

Another of the legislators who worked on the imitation drug bill is Del. Harvey Morgan, a Gloucester County pharmacist.

"This bill will make it illegal to manufacture or distribute a pill that looks like a controlled substance," he said.

Even if the distributor tells the purchaser the contents of a "lookalike," he will be guilty of a misdemeanor, Morgan said.

Virginia Beach Commonwealth's Attorney Paul Sciortino said no action can be taken against anyone selling "lookalikes" until July 1.

"Unless it's some type of emergency legislation, it will not go into effect until July 1," Sciortino said. "And that means whatever they're doing now is legal.

"But I can assure you if the legislation covers what they're selling, come the first of July, it will be enforced."

Attachment #3

'Rip-off' drugs fool buyers, pose health hazard

By BILL REED
Virginian-Pilot Staff Writer

Shortly before 1 p.m. on May 25 a 17-year-old Western Branch High School girl went to the school nurse complaining of a severe headache and of feeling feverish.

She was rushed to Maryview Hospital for observation, and Chesapeake police were called to investigate after she told the nurse that she had taken two "black beauties," or amphetamine capsules, almost two hours earlier.

She got the capsules from another student at the high school, she told school officials. They learned that four capsules had been bought from still another student for 25 cents apiece.

The information, and a bag full of confiscated capsules, were passed along to police investigators.

Chesapeake narcotics detectives sent a sandwich bag containing 11 capsules to the Tidewater Regional Forensic Laboratory for analysis, and they learned several days later that the drugs were not amphetamines, but a caffeine derivative that is available without a prescription.

It came as no surprise to Lt. Donald Zeagler, who heads the special investigation bureau of the Chesapeake Police Department. "We're finding more of that stuff every day," he said. "We call 'em 'rip-off pills.' You can buy them in head shops, or you can get them by mail order."

They are nonprescription substances that some enterprising individuals buy in quantities of 10 to 12 boxes at a time, usually through a mail-order distributor, and sell for 50 cents to $1 a capsule, he said.

"We got a 16-year-old kid at one local school who had $900 in his pocket," Zeagler said. "He said he had only been in business three weeks. He had some rip-off drugs and some pot on him."

While Zeagler calls them rip-off drugs, pharmacists call them "look-alike" drugs. On the street they are known as "turkey speed." By any name, Zeagler explained, they are simply drugs that are repackaged, usually at licensed out-of-state plants, to look like controlled substances such as amphetamines or barbiturates. Unsuspecting buyers, many of them young and unfamiliar with illicit drugs, are duped into believing that the look-alikes are the real thing.

Prior to July 1 — and much to the consternation of police officers such as Zeagler — Virginia had no law prohibiting trafficking in these capsules.

But the 1982 General Assembly passed a measure, the "Imitation Controlled Substance Bill," that makes it a Class 1 misdemeanor to sell over-the-counter drugs packaged to resemble prescription drugs, particularly those in capsule or pill form, according to Del. Harvey B. Morgan, R-Gloucester, a pharmacist who was one of three patrons of the bill.

The real danger of the rip-off or look-alike drugs is that they pose a serious health hazard, said Zeagler, who cited cases throughout the nation in which teenagers have suffered strokes or cardiac arrests after taking six to 10 capsules. In many cases, the victim had increased his intake of the look-alikes because one or two capsules did not give him the high or low he was seeking.

But even a small dosage may be harmful to some people. "You get a kid who has high blood pressure or something, he eats a couple of those things, and it's all she wrote," Zeagler said.

The 17-year-old Western Branch High School student was a case in point, said Zeagler, although she was released from the hospital and returned to classes several days later.

"There were something like 12 deaths last year nationwide because of this," said Morgan.

"The problem has been that police would arrest someone who had what looked like a controlled substance. They would find on analysis that the stuff contained caffeine or phenylpropanolamine, an over the counter product — a decongestant. So they would drop the charges because the person didn't have the substance they were charged with having. The problem proliferated so much that they stopped making arrests.

"And, that led to a number of young people, even down to elementary grades, purchasing these drugs thinking they were the legitimate thing."

The law, which carries a maximum penalty of 12 months in jail and a $1,000 fine, is a compendium of four separate bills, three from the House of Delegates and one from the Senate. It received the endorsement of state prosecutors, sheriffs, police, nursing, medical and pharmaceutical associations, said Morgan.

There was almost no opposition to the measure, said Del. George Heilig, D-Norfolk, who serves on the House Courts of Justice Committee. He recalled only token resistance from "one or two civil libertarians, who felt that it might jeopardize some of their rights."

John Hasty, another Gloucester County pharmacist, helped Morgan and other legislators pass the measure by supplying data he has accumulated on the subject of drug abuse from state and local law enforcement authorities over the past three years.

With the help of Newport News police, Hasty learned that capsules are manufactured by legitimate companies, which buy empty capsules from other legally licensed businesses.

These products are distributed to local retail outlets, or individual entrepreneurs, whose orders usually are generated by magazine advertisements for "perfectly legal" stimulants, Hasty said.

At present, the most active drug-manufacturing and distributing center of this kind is Lewiston, Pa., also the hub of a heavy East Coast trucking traffic, local police departments said. Fifty so-called drug plants, most of them the basement or garage variety, sprang up in this crossroads community in the last three years, authorities in Virginia have discovered.

Look-alike drugs are composed of one or three kinds of nonprescription drugs, Hasty said. They are ethedrine sulfate, caffeine or phenylpropanolamine, and can be found in diet pills, stimulants, cold tablets and decongestants.

But over-the-counter, commercial preparations containing these ingredients are not packaged to look like controlled drugs, Hasty explained, and therefore are not covered by the new law.

The three substances are packaged individually or together in the look-alikes, he said. "If too much gets in the system, you could end up having a stroke, because it makes the blood vessels in your brain swell. Also, you could have a heart attack."

Hasty's research has revealed that there are in the United States two surviving stroke victims, whose difficulties have been attributed to the abuse of look-alikes. "One is a young man from Philadelphia who has been unconscious for several months. Another is a young lady from Texas who did come out of it, but who is partially paralyzed," he said. "The state of Illinois in the last five months of 1981 recorded six deaths because of look-alikes," he said.

"We've been fortunate in Virginia," he said. "We haven't had any deaths that we could document."

A statistical picture of of the look-alike victims in Virginia is hard to establish, Hasty said, because the state has been unable to specify the number of deaths or overdose cases attributable to the abuse of noncontrolled drugs. "But," he added, "there have been some cases listed so as being possibly related to look-alike drugs."

Alcohol or illegal drugs often are taken with the look-alikes, he said, making it difficult to identify the cause of the victim's stroke or death.

Hasty's observations are borne out by Robert J. Campbell, director of the Tidewater Regional Forensic Laboratory. "We haven't been keeping statistics on look-alike drugs, although lately we have been getting more of them."

Hasty and Zeagler see the making of another trend in the ever-changing illicit drug market. "There's been so much look-alike stuff on the streets there has been a tendency by police departments to decline to make arrests," said Hasty. "Police are encountering a product that is at first glance a look-alike, but really is a controlled pustence," he said. "These cats have taken the look-alikes and put the real stuff in there."

Staff photo by Karen Kasmauski

Police Lt. Donald Zeagler shows confiscated drugs.

A recent spate of publicity seemed to slow the traffic in look-alike drugs, even before the new law took effect, Hasty said.

This trend is verified by Sgt. J.G. Malesky, who heads the narcotics bureau of the Virginia Beach Police Department. "It was prevalent in the schools at one time," he said, "but it kind of died down since some news stories have appeared." In Norfolk and Portsmouth, police have noted no dramatic increase in the look-alike drug trade among young people. In fact, said Norfolk Youth Bureau Capt. R.A. Sawyer, "We are very pleased to tell you we didn't have a drug case in the schools for the last several months."

While there has been some traffic in look-alikes among Portsmouth teen-agers, it most often is in conjunction with marijuana use, said Sgt. C.G. Bower, a member of the narcotics bureau.

"LOOK ALIKES", "PICK ME UPS"
"STIMULANTS"
"NON-PRESCRIPTION DRUGS"

EXTRACTED FROM COMMENTS

MADE BY

ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON CRIME

COMMITTEE ON THE JUDICIARY

HOUSE OF REPRESENTATIVES

OCTOBER 14, 1981

"Look Alike Drugs"
Background Information

The issue of "Look Alike" drugs arose when a number of small drug manufacturers began to manufacture drug products that mimicked, through size, color, shape and other markings, various prescription drug products that contain scheduled substances, such as amphetamines, barbiturates and tranquilizers, which are regulated under the Controlled Substances Act. These over-the-counter (OTC) look-alike stimulants, or "uppers," contain either a combination of ingredients such as caffeine, phenylpropanolamine and ephedrine or caffeine alone. The OTC look-alike sedatives or "downers" usually contain one or more antihistamines. Because these OTC look-alikes do not actually contain controlled substances, but only look like they do, they escape regulation under the Controlled Substances Act.

Furthermore, at the manufacturers' level the OTC look-alikes have been labeled correctly as to active ingredient content and the packages are in compliance with the Food and Drug Administration's (FDA) current OTC drug labeling requirements for use as decongestants, bronchodilators, and over-the-counter stimulants to aid mental alertness. These manufacturers, who are properly registered with FDA, sell to drug distributors, usually on a contract basis, and manufacture the drug products to distributor specifications.

The promotion of these drugs is different from normal drug industry practices. The distributors advertise in ways that are attractive to the youth of the country which depict products as legal stimulants or sedatives. Also, the OTC look-alikes are sold retail to consumers unlabeled and because of their physical appearance, the buyer is led to believe he or she is purchasing a controlled drug.

The manner in which these products are manufactured and distributed presents a special enforcement problem for the federal government. Because the drugs in question are OTC products, they escape the control of the Drug Enforcement Administration (DEA), the federal agency responsible for regulating drug abuse at the "street" level. Conversely, since FDA's main focus is at the manufacturing level, the street abuse aspects of the problem are outside of the Agency's normal enforcement activities.

PUBLIC HEALTH PROBLEM

The rapid growth of the OTC look-alike drug traffic is a recent phenomenon. The FDA is unaware of any health care value or service this fringe industry offers to the consumer. The OTC "look-alike" products have infiltrated secondary schools and college campuses. Children and young adults, though not actually taking controlled drugs, are developing drug abuse habits which may lead them to use of the habit-forming "hard" drugs. Further, the promoters of these drugs state they are "100% legal," suggesting a societal blessing to a recreational use of drugs and counteracting the effect of the many drug educational programs supported by government and public organizations for many years. The FDA has received numerous telephone calls from parents whose children have received unsolicited literature in the mail from distributors promoting these OTC look-alike drugs. Clearly, OTC look-alikes have become part of the drug abuse problem in this country. To date, there have been 12 reported deaths in which these drugs are associated. In most cases, where the cause of death can be specifically identified, it has been attributed to caffeine intoxication.

The presence of these OTC look-alikes also hinders federal, state and local law enforcement authorities' efforts to control illegal distribution of prescription controlled substance drug products. Law enforcement authorities have often spent considerable time, effort and resources in pursuing

what appeared to them to be illegally distributed prescription controlled substance drugs, only to find that the drug products were in fact OTC look-alike products.

Finally, the medical community and poison control centers are hampered by the OTC look-alikes in providing proper medical care and correct antidote treatment in overdose cases, since they are also likely to be mistaken as to the true identity of the drugs in question.

FDA has encouraged and supported states in their actions to deal with this problem. Currently, 14 states have either passed legislation or have legislation pending banning distribution of OTC counterfeit drugs.

Senator HUMPHREY. Thank you, Ms. Delaney.

Chief Hopkins?

Mr. HOPKINS. First of all, Senator, I would like to thank you for inviting me here. I have been aware of what has been commonly worded here as look-alike drugs for 5 or 6 years now. I have been in law enforcement for 25 years, and a great deal of it in investigation of drugs.

In the State of Connecticut, I was with the SOCTF organization, the State organized crime task force, for almost 11 years in investigating drugs of this type. Since I have been the chief of police in the small town of Littleton, N.H., since December 22, 1980, I have observed an upswing in the look-alike or act-alike drugs in that particular area.

On December 30, 1982, one Darcy Enderson, a graduate of Littleton High School, very much an athletic girl, a very beautiful person both inside and out—a person who was involved with sports in her school; she was a coach in basketball, soccer, and very much involved in school sports. She also worked a part-time job.

Because of all the activity, she became tired and instead of eliminating some of her responsibilities and releasing those responsibilities to someone else, she kind of bowed to peer pressure.

Senator, let me tell you, there is nothing greater to turn the head of a youth than peer pressure in a school. This particular individual was a very strong-minded girl, and yet she bowed to peer pressure and commenced to use drugs in order to get the energy she needed to continue on. This, along with some alcohol, on December 29 and 30, ended in her tragic death at the age of 19.

I do not want to go into the total investigation in the Enderson file; it is all there for you to read in the 50 copies I left with you. But I will say further that this department, and specifically myself, is not finished with this case and it is my intention to attempt even at this late date to arrest the distributor of those drugs—purple hearts, specifically—that caused the death of Ms. Enderson.

As you may already know, Senator, the State law that we presently have in the State of New Hampshire, most recently passed through the efforts of Ms. Sytek and Ms. Polson, does not cover the

situation if the drug is said to be exactly what it is, and that is that it is not a controlled substance; that it is a lookalike and that it is ephedrine or caffeine.

Therefore, there is nothing legally that I can do about it under that statute, at least. We are attempting at this particular time to look into other statutes; for instance, negligent homicide.

Experience has shown me over 25 years that pressed by legal authority, the illicit market will devise other means to subvert the youth and the use of drugs. Since the fifties when drugs were quite evident, it has become more and more sophisticated in its manufacture, its concealment, and distribution of drugs.

The problem of drugs has not, in my opinion, become any less of a problem in the Northeast. What has happened is the illegal manufacturer and distributor has become even more careful in his illegal business and has taken advantage of our U.S. Constitution to thwart law enforcement to curb such illegal trafficking of controlled substances and noncontrolled substances.

Their answer to our control and enforcement of controlled drugs in the market is the marketing of look-alike or act-alike drugs. There is no doubt in my mind or those experienced in drug investigation that look-alike drug manufacturers are backed by organized crime in the form of management, money, and advertisement. It is their expertise in subversion of our laws, at least in my belief, that has created the market for look-alike drugs.

If we look into our records, we note that more and more look-alike drugs are sold through advertisement in many of our more popular magazines. For example, in this particular case of Darcy Enderson, the distributor, or seller, or "street horse," if you will, told me that he phoned a number in Massachusetts and bought these drugs. He sold 100 purple hearts to Darcy Enderson for a cost of $20.

They are manufactured, Senator, for about a penny to a penny-and-a-half apiece, so we are talking about 1,000-percent interest rate, or better. It is quite a moneymaking situation.

The look-alike problem, in my opinion, has continued to be a problem in the Northeast, and it will continue to be so during the next couple of years, I believe. I think the flow seems to be, and has always been, in my experience, from the west to the east coast for some reason.

And although perhaps—and I do not have anything to prove this—it is slowing down on look-alikes on the west coast, it is on the upswing here on our coast.

The immediate problem that exists at this particular time is not really the look-alike, as has been brought out here in other testimony, but those that act alike. The danger is ever present.

The danger, Senator, is simply this: the drug culture, or the youth of our schools who for one reason or another feel that they have to have an out—an escape route, if you will, in order to get through a day—will believe just about anything anybody will tell them simply because they are uneducated in the facts.

One of the biggest problems we have is the uneducated public. I do not want to get off into someone else's territory here, but I think an educational program is more than important in this particular situation.

The problem that simply exists is, in dealing with these particular drugs, when sold by a "street horse" to a child or a youth in a school, it is being sold as speed. The understanding of speed is amphetamine.

If you look at the file I gave you, sir, there is an amphetamine-speed advertisement by the T. R. Mc Wit Co., Post Office Box 6384, Lakeworth, Fla. This is the same advertisement, sir, that Ms. Sytek referred to before.

It is most interesting to me that they tell them how safe it is, how legal it is, and, boy, can you make yourself a buck. As my colleague has stated, it is all a matter of economics.

Senator, I have listened to people talk about what should and what should not be done, and who is going to handle it. I am here to tell you we are too late; we are way too late. Too many people have died; too many more will. We are way too late.

Absolutely, it is my opinion, and only my opinion, that in the past FDA has had this experience. They have had changes in their laws to drop from three drug situations; they are now down to two. What is to prevent them from going further?

On that same situation, how about packaging identification for the manufacturer of these drugs so that, as my colleague has said, we can find out who sold it and what the danger is involved?

Why are there no warnings involved in these drugs in their sale? Why are they not packaged with warnings on them? After all, we have warnings for cigarettes. Why can we not have a warning device situated in these cases?

Also, I believe there should be a violation for sale of these drugs outside of their original package. It is presently the law in the States that if you sell a prescription drug outside of its package, you can be arrested for this. It gives us another tool with which to work.

The other thing that has been brought up very well is an age limitation. I think that most interesting to me has always been that organized crime does not do anything that is going to cost them money—not a thing. They are in the business to make money. Life and death has no meaning for them. The only thing is how much money can we make?

But if they have to manufacture look-alike or act-alike drugs at more than it costs for the real McCoy, they are going to go out of business. More importantly, the "street horse" or seller will not be able to afford it, since they can buy the legal drug or the illegal drug at a cheaper rate.

The only way you are going to beat this, Senator, is hit them in the pocketbook, and that is the only way I can see it being done. That is only my experience talking, nothing more and nothing less. But it is a way of going and it is only a suggestion.

Thank you.

[The prepared statement of Mr. Hopkins follows:]

Police Department Littleton, New Hampshire 03561

TELEPHONE 603-444-2422

"Business Center of the White Mountains"

MARSHALL L. HOPKINS, *Chief*

July 11, 1983

Senator Gordon Humphrey
U.S. Senate Committee
Drug and Alcohol Abuse
Washington, D.C.

Subject: National Distribution
Re: Manufactured Look Alike Drugs

Dear Senator Humphrey,

Enclosed you will find a copy of a case file of one Darcy Enderson of Littleton, New Hampshire. This case file is forwarded to you and your colleagues for your parusal, in the hope it will cause immediate action in passage of Federal Legislation for control of interstate transportation of look alike drugs and/or making it illegal to use the mail for the purpose of trafficing in controlled and non-controlled drugs.

I have been aware of look alike drugs for some years now (about six years) and have seen an upswing in their use over that same period. Since becoming the Chief of Police of Littleton New Hampshire, I have noticed an even greater trend toward look alike drugs in our school systems.

Darcy Enderson was a graduate of Littleton High School in 1981. She was very much liked, athletic girl, who was considered to be a beautiful person, both inside and out. There is no question that peer pressure had a great deal to do with her use of alcohol and drugs. She worked while in school and was involved in both coaching and playing of basketball, softball and other sports. Because of all this activity she became somewhat tired. Instead of releasing some of her responsibilities to other graduate students, so she could get proper rest, she bowed to peer pressure and began using pills to compensate for her lack of energy. This along with alcohol eventually caused her demise on December 30, 1982 at the age of 19 years.

I won't go into our total investigation in the Enderson case, it is all there for you to read. I will state further, however, that this department and more specifically this investigator, is not finished with this case. It is my intention to attempt, even at this date, to arrest the distributor of the look alike drugs (Purple Hearts) which caused the death of Darcy Enderson.

As you may already know our State Laws did not allow for arrest under 318-B at the time of this tragic death, since this statute only covered "Controlled substances". This, of course, is the major problem in every state in our union. We will therefore attempt to arrest on Negligent Homicide, but feel we may lose the application for warrant, because of the wording of that particular statute. We continue to try just the same.

Experience has shown that when pressed by legal authority, the illicit market will devise other means to subvert our youth into the use of drugs. Since the several states have become so involved in stamping out of our drug problems since the 1950's, it has become more and more sophisticated in its manufacture, concealment and distribution of drugs. The problem of controlled drugs has not, in my opinion, become any the less of a problem in the Northeast. What has happened is the illegal manufacture and distributor have become ever more careful in their illegal business, have taken advantage of our U.S. Constitution to thwart law enforcements efforts to curb such illegal trafficing of controlled drugs.

There answer to our control and enforcement of controlled drugs, in the market of "Look alike" drugs. There is no doubt in my mind or those of experienced in drug investigation that look alike drugs manufacturers are backed by organized crime in the form of management and money and advertisement. It is their expertise in subversion of our laws, at least in my belief, that has created the market for look alike drugs.

If we look into our records we note that more and more look alike drugs are sold through advertisement in many of our more popular magazines. Playboy, Penthouse, High Times etc. These are aimed at those persons in the "drug culture". These look alikes are then sold to those persons who have been experienced in the past with trafficing in illegal drugs. They are sold at $1.00 per hit on the street by street "runners" for the distributor (local). You will note in this case file one such advertisement which gives cost to dealer, street value prices and wording necessary to be within our present laws. The look alike problem has continued to be a problem in the Northeast. It is said that it is beginning to slow down, but, we find that the flow began in the west, more specifically California. That at present this problem may be slowing there, but is heavier on the East Coast. This is because the natural flow is from west to east. History has shown most new drugs seem to appear in California and eventually move eastward to our coast. Therefore I, foresee a continued upswing in the Northeast of look alike drugs for perhaps another year or so. It certainly shows that trend in our school systems at this writing.

I believe the main problem of look alike drugs, is as obvious as the day is long. If, I as a manufacturer or distributor or backer for that matter, can cause the youth of today to become "hooked" on a "look alike" drug of Ephedrine and Caffeine there will come a time when that thrill, dream world or "high", if you will, will not be enough for the abuser. Soon the abuser will need some drug more powerful to gain the same or even greater high. Needless to say, there in lies the reason for organized crime to become involved in the "look alike" business. Lets face it "look alikes" are manufactured at about one to one and one half cents apiece and sold by the thousands to street distributors for (10) ten cents apiece, making a clear profit of approximately 700 to 1,000% per bottle of 100 hits. It doesn't take a genius to figure out the millions of dollars being poured into organized crime coffers by means of "look alike" drugs. Nor does it take genius to realize sooner or later the abuser will be paying even higher prices for the real McCoy drugs which he will most assuredly need in order to gain the same results. This is the underlying reality we must face.

Because the "look alike" is said to be "safe", the abuser also fails to realize the danger involved in it's use. They are not told of the danger when mixed with other drugs or alcohol. They are not told about Tachticardia or "rapid heart" or its effect on high blood pressure when taken in overdose. This is

what caused the death of Darcy Enderson of Littleton. They are told it is "safe" and basically harmless and our drug culture youth, unfortunately are gullible and have a tendency to believe this sort of advertisement.

We have, since the death of Darcy Enderson, passed legislation to cover "look alike" drugs which are sold as "speed" (amphetamine or barbituate) but, there in lies a problem also. Let's suppose the street "horse" tells the potential buyer that he is buying "look alike" drugs. Under our State Statute, he is immune to prosecution because he did not say it was "speed" or amphetamine, etc. The danger is still there, the buyer is not warned of the potential danger or potential death. No care is taken to make sure the buyer is healthy and even if he or she were healthy, no warning is issued to avoid mixture with other drugs or alcohol. Therefore, it is impossible for us to curb the sale of "look alike" drugs which are sold in this fashion. We must hope, that the street "horse" makes the mistake of saying "speed" or "rush" or amphetamine in order to prosecute.

It is therefore my considered opinion and those of other law enforcement authorities, that the advertisement and interstate sales and distribution of "look alike" drugs by use of the mail, should be made a Federal Offense. This would most assuredly put an immediate halt to such advertisement and distribution. This legislation would give both Federal and local authorities another tool with which to fight organized crime underground drug culture. If we fail to do so, it shall be to their advantage and the advantage of our international enemies, who are bent on the subversion of our youth through drugs and the ultimate distruction of our nation and freedom of human kind throughout the world.

Respectfully submitted,

Marshall L. Hopkins

Marshall L. Hopkins, Sr.
Chief of Police
Littleton, New Hampshire

(NOTE: In the interest of economy and due to printing limitations, certain appendix material accompanying Mr. Hopkins' prepared statement was retained in the files of the committee where it may be researched upon request.)

Senator HUMPHREY. Thank you. I think your experience is a valuable source for us.

Mr. Grant?

Mr. GRANT. Thank you very much. The look-alike drug problem hit our school district in October 1982 at a high school dance that we were chaperoning. We made a drug bust and, when confronted, I took away from a student a plastic bag of sweethearts. It was my job to have the student arrested because he thought he was selling speed and so did we.

When taken to the local pharmacy and hospital, they too were unable to identify what these pink pills were. The police notified us that they were unable to make an arrest because the pills were not illegal.

The superintendent of schools, Dr. Robert Reidy, was unable to bring any action against the student because our school district policy did not cover look alikes or any type of imitation controlled substance.

As part of the punishment to the boy, he had to sit down with a group of administrators and educate us, and it was an education. He told us that the pills that the students are using now are considered to be a jock's best friend, in that the athletes were using them for that extra burst of energy.

Dr. Reidy asked me to do some research on the subject of look alikes and report back to him with a policy change. And with information that I was able to get from Senator Humphrey's office, the local pharmacist, local and State police, teachers, and administrators, we formulated a district policy.

I would like to mention right now that I feel that the wording of our policy is very, very much in line with the bill that you are proposing because it addresses the action of the substance. I feel that your bill is attacking look alikes and attacking imitation controlled substances, but it is attacking act alikes because you are focusing in on the action of the substance, and I feel that is the key.

I want to read the wording of our school board policy:

> No one shall possess or ingest alcohol or a controlled drug, nor be under the influence of alcohol or a controlled drug or any chemical in any form, such as look-alikes or other imitation controlled substances, used for recreational mind alterations or other non-medical purposes.

Upon further investigation, we found that the problem in New Hampshire was not our problem alone. In Time magazine, September 21, 1981, there was a good article about the number of deaths. I was not aware that we had a death in New Hampshire, in Littleton, until I was notified by your Senate office to that effect.

Further questioning of students and information from school health officials showed that these pills are available in many varieties to anyone who wants them. The student who had distributed these pills at a dance had gotten them from an adult.

When we talk about it being a student-child problem, we certainly can admit that the students are the beneficiaries of this wonderful new concept, but it is an adult issue and it must be stopped in the adult stage.

I went to the various bookstores and asked if they would be willing to pull the magazines that are showing these ads. The top-shelf

magazines basically were the ones that were carrying the ads last fall.

The magazines, like homosexual magazines, lesbian magazines, and other pornography magazines, carried the ads. I think we need to note now that other magazines have jumped on the bandwagon, and Cosmopolitan certainly is cashing in on the advertisements for the pink sweethearts, the jock's best friend.

Something else that I want to mention about the advertising is that National Enquirer has an ad that probably has a piece of everything that has been said this morning. They have a starter kit, so people can call up and get a starter kit that is a sample. They advertise that they want people to write for free samples so that they can become dealers, distributors, and salespeople.

Something else that was given to me by a representative from Salem—I was looking for one of these samples of the pink football. They are advertising here the pink football. Now, certainly, to call a pill a pink football and put it in the shape of a football, they are not after the housewives or the cheerleaders. They are after the athletes who would be students, so the advertisers are going for symbolism and when the students are seeing the pink football, they are getting the idea that this is for the athletes.

The hospital and ambulance personnel cannot identify the substances. As an ambulance attendant myself, when we have a drug overdose we try to bring a sample of the medicine to the hospital. The medical profession is at an unfair disadvantage in rendering medical assistance. A remark that was made by hospital personnel said we would have to stock one of every pornography magazine on our shelves to know that, yes, indeed it is an act alike, or a look alike, or an imitation controlled substance, and then what good would the information do because we do not know what the substance is?

Our pharmacist says that they are of inferior quality, and if you look at the material that these are made out of, there is no guarantee that the consistency of one pill would be consistent from one pill to the next in the same batch that is sold.

Our superintendent of schools distributed a copy of what we call our enlightened school board policy to every school board in the State, and we hope that all of our school systems will adopt it.

We are trying to fight it on a local level. When we passed some ordinances on our amusement centers, we changed the wording from "no amusement center shall allow alcoholic beverages or legal drugs on the premises." We successfully amended it to include look alikes, imitation controlled, or any substance that is used for recreational purposes.

I feel we need to have action taken at absolutely every level, and I feel that your bill that focuses on the action of the substances will indeed address the act alikes.

When the police chief was talking about the FDA changing from three substances to two, I need to throw out that in my humble opinion, that is absolutely not going to be the answer. Right now, the kids know that you can buy this drug over here which is legal, go to the pharmacy and pick your Contac cold capsule up, pop it open, tweezer out the blues, mix the blues with this one over here, and you have your high.

As soon as the FDA regulates the two chemicals in one pill and has it come under their jurisdiction, then what the drug companies will do is stand back and manufacture a pill with one chemical over here and a pill with one chemical over here and one over here, sell it as three separate chemicals, and discretely get the word out on the street that you need to buy all three, mix them together, and you have the action of the substance. I think that that is a point that we need to somehow get to the FDA.

In closing, I would like to say that as a New Hampshire native, we certainly are proud that it is a Senator from New Hampshire that is leading the fight that is endangering every single household in America, and that the problem is national and it is increasing.

I thank you for inviting me, Senator.

[The following was received for the record:]

TO: Senator Gordon Humphrey

FROM: C. James Grant, Temple Elementary School Principal

SUBJECT: Look-Alike Drugs

DATE: July 14, 1983

The look-alike drug problem surfaced in the Contoocook Valley Regional School District in October of 1982 at a high-school dance which my wife, who teaches at the high school, and I were chaperoning. A "drug-bust" of sorts was made at the dance when I witnessed a student passing money secretively in exchange for an unidentified substance. When confronted, I took from the student a plastic bag of "sweethearts". As chaperone, it was my job to follow school policy and contact the police. The police were unable to identify the pills.

When taken to the local pharmacy and hospital, they too were unable to identify what these heart-shaped pink pills were. The police notified us that they were unable to make an arrest because these pills were not considered illegal.

The Superintendent of Schools, Dr. Robert Reidy, was unable to bring punative action against the student because the school policy did not cover imitation controlled substances. However, as part of the boy's punishment, he met with a group of administrators and "educated" us about the substance abuse problem in our district high school. We soon learned that these hearts were a "jock's best friend" and that many of our athletes were using them before sporting events, particularly running events. The hearts contained a substance that seemed to give a student a life.

Dr. Reidy asked me to do some research on the subject of "look-alike drugs" and report back to him with a proposed policy change. With information from Senator Humphrey's office, our local pharmacist, local and state police, teachers and administrators, we were able to formulate a district policy to deal with look-alikes.

(See Appendix-A)

Upon further investigation, we found that New Hampshire was not alone in a look-alike drug problem. TIME magazine, September 21, 1981, page 69, refers to deaths from young people becoming victims of overdosing.

(See Appendix B)

Further questioning of students and information from the school health personnel showed that these pills are available in many varieties to anyone who wants them. The student who was caught at the dance purchased them from an adult in the community! Having thought these were available mostly through pornographic magazines, we were surprised when my wife was looking at COSMOPOLITAN magazine and there was an advertisement for the Hearts!

(See Appendix C)

These ads are now found in wrestling magazines which students buy as well as in most "top-shelf" magazines. Students have no difficulty purchasing sample "Starter Kits" over the telephone. The ads have gone so far as to use symbolism: In the March 8, 1983 issue of THE NATIONAL INQUIRER on page 27, pill #7 is advertised in the shape of a pink FOOTBALL! Our local pharmacist has seen pills in this shape here in town. Also in the same advertisement one can send for free samples an the advertisement also is soliciting for "dealers, distributors and salespeople."

The hospital and ambulance personnel cannot identify these substances with the pharmaceutical manuals which are available presently. As an ambulance attendant myself, when we have a drug overdose, we try to bring a sample of the medicine taken along with the patient to the hospital. The medical profession is certainly at an unfair disadvantage in rendering medical assistance to abusers when they too, cannot identify the pills.

Superintendent of Schools Reidy has made available our enlightened drug policy to all of the school districts in the state of New Hampshire.

The next step, in my opinion, is to give the authorities outside of school a basis for stopping this activity. We are attempting to attack this problem locally. At our local town meeting in Peterborough, NH in March of 1983, an ordinance was voted upon to regulate amusement center activity. I successfully amended the original proposal to include look-alike drugs along with alcohol and illegal drugs banned from these amusement premises.

Article 15: Town of Peterborough, March 15, 1983.

. . .

"4. Prohibited Practices:

A. . . .

B. No amusement center shall allow alcohol beverages or illegal drugs upon the premises."

The above is the way the original ordinance was written. Below is the adopted amendment:

Article 15:

Amend Section 4B by striking out the same and inserting a new Section 4B as follows:

"No amusement center shall allow alcoholic beverages or illegal or "look-a-like" drugs upon the premises. A "look-a-like" drug is any chemical in any form such as "look-a-likes" or any other "imitation controlled substance" used for recreational, mind alteration or other non-medical purposes."

We need a law which will attack this problem totally--availability of these look-alikes, advertising, sale to minors, use of United States mail to sell these, and penalty for illegal use.

Respectively submitted,

C. James Grant
Principal, Temple Public School

APPENDIX A

OFFICE OF THE SUPERINTENDENT OF SCHOOLS
Peterborough, New Hampshire

PROPOSED DRUG AND ALCOHOL POLICY

I. No one shall possess or ingest alcohol or a controlled drug, nor be under the influence of alcohol or a controlled drug or any chemical in any form such as "look-a-likes" or any other "imitation controlled substance" used for recreational mind alterations or other nonmedical purposes during or en route to, or from, any school sponsored event.

Any student found to have violated this rule may be suspended from school for twenty (20) days. Any student found to have violated this rule for a second time within one school year shall be reported to the school board with the recommendation that he be dismissed for a period not to exceed one school semester.

II. School administrators may administer accepted physical tests to determine whether a student has ingested alcohol or a controlled drug or any chemical in any form such as "look-a-likes" or any other "imitation controlled substance" used for recreational mind alterations or other nonmedical purpose.

III. No person shall sell, share or give to another student alcohol or a controlled drug or any chemical in any form such as "look-a-likes" or any other "imitation controlled substance" used for recreational mind alterations or other nonmedical purpose, on school property during school hours; or while participating in an interscholastic event or any exercise sponsored by the school or enroute to or from such event or exercise in transportation provided by the school.

Any student found to have violated this rule shall be suspended from school for twenty (20) school days and shall be reported to the school board with the recommendation that he be dismissed for a period not to exceed one school semester. These penalties may be increased in the case of students who are "dealers".

IV. Any student found to have violated either of the foregoing rules will be required by the Superintendent to participate in an approved program of education and/or treatment in the abuse of alcohol, drugs, or chemical substances, prior to his being allowed to resume attendance at school.

V. Each violation of the foregoing rules shall be reported to the local police for appropriate action. Persons under 20 years of age are forbidden by statute to possess or consume alcoholic beverages. Persons of the age of 20 or more are forbidden by statute to provide alcoholic beverages to persons under 20.

All violations of this policy will be reported to the Board by the Superintendent.

Methcathe

Real Life, Reel Life: Methcathinone, left, has a reputation nearly as deadly as that of the real thing

"Look-Alikes": a New Drug Danger

Fake amphetamines are not only lethal but legal—for now

The 17-year-old girl in Belvidere, Ill., seemed to be just one more victim of an overdose of illegally obtained amphetamines. Police finding the type of pills that allegedly killed her, thought they looked just like "black beauties," one of several forms in which amphetamines are sold. Analysis showed, however, that they were not amphetamines at all but a combination of substances commonly found in the cold remedies, diet and keep-awake pills sold over the counter in drugstores. The dead girl was a victim of the nation's latest drug danger, the "look-alike" pill.

Though they are made to mimic the appearance of the more expensive amphetamines, look-alike drugs contain no federally controlled substances (*i.e.*, with a high potential of dangerous abuse). Their primary ingredients are caffeine, a stimulant; ephedrine, a vascular constrictor; and phenylpropanolamine (PPA), a chemical cousin of amphetamines. The danger lies not in the kinds of chemicals they contain but in the amount. Whereas the average diet-aid capsule may contain about 50 mg of PPA and between 100 mg and 200 mg of caffeine, a look-alike capsule can carry 50 mg of PPA and 200 mg or 300 mg of caffeine, which is nearly enough to cause heart or respiratory failure.

Dr. John Spiker, an Illinois toxicologist: "People hear caffeine, and they think of a cup of coffee. You get between 90 mg and 100 mg in a cup of coffee. The people we're seeing using the look-alike drugs are taking ten to 20 pills at once." In other words, they can invert the caffeine of dozens of cups of coffee at one gulp. In the past two years, look-alikes have been involved in the deaths of at least 11 people in New York, Maryland, Michigan, New Mexico, California and Illinois.

For the small manufacturers who deal in look-alikes, the product yields a lot of money with little legal risk. Says Lieut. Robert Long of the Massachusetts state police narcotics unit: "A dealer can buy about 1,000 look-alike pills for $45 per jar, or approximately 4¢ each. Then he goes out to some eighth-grader and sells those same pills for $2 apiece. Right off the bat he's making a profit of more than $2,000."

Ads for mail-order look-alikes ("safe, effective and *legal*") have appeared in publications like *Cosmopolitan* and Chicago's *Reader* and in leaflets passed out at rock concerts and in schoolyards. Ironically, the only instance in which it is not *legal* to make or sell them is when a manufacturer or dealer claims they are real amphetamines. In that case he can be prosecuted for fraud. But sellers carefully label look-alikes as "stimulants" and often include warnings about maximum dosage. Says Lieut. Long: "Most of these guys are not going to make the mistake of claiming to have something they don't. They just let the kids think they have it."

Because the drugs are not mislabeled by the manufacturer the Food and Drug Administration, which is responsible for the safety and efficacy of drugs, can do nothing under present laws. Neither can the Drug Enforcement Administration, which applies law only against illegal use of controlled substances. But the U.S. Postal Service has filed complaints against 39 mail-order companies, charging them with misrepresenting the safety of their products. Delaware was the first of several states to pass special statutes against look-alikes. Known as "turkey" laws, so named because "turkey" is the street term for phony drugs. Probably no serious headway will be made, however, until the Federal Government finds a way to block the look-alike loophole with a uniform national law. ■

APPENDIX B

Testes Test

A self-exam for cancer

Each month, millions of women perform breast self-exams for suspicious lumps in an effort to detect cancer early. Now doctors are urging men to perform a monthly self-examination of their own, this one aimed at cancer of the testicle.

The disease, though rare, is occurring with greater frequency. In the past 40 years, the incidence of reported cases has almost doubled in the U.S. Today it affects about four of every 100,000 men annually; an estimated 4,000 new cases are diagnosed each year. Once found primarily in older men, it now is the most common form of cancer in men between the ages of 20 and 34, causing 9% of all male cancer deaths in that age group.

No one knows why testicular cancer is increasing—or indeed why it strikes. It appears most frequently among white middle- and upper-class men. Two groups run 40 times the normal risk of developing the disease: men with a testicle that failed to descend from the abdominal cavity into the scrotum, a lapse that normally occurs during development of the fetus; and men with a testicle that descended only after they were six years old. Preliminary studies suggest that undescended testicles may be more frequent in boys born to women who received the hormone diethylstilbestrol, or DES, during pregnancy. The hormone was widely prescribed in the 1940s and 1950s to help prevent miscarriage.

Researchers at the University of California at San Francisco are beginning a three-year study of 250 patients with the disease to explore the connection with DES as well as other possible influences, including race, social class, on-the-job exposure to chemicals, even the type of underwear favored. One theory holds that men who wear tight shorts run a greater risk of developing the disease.

Although testicular cancer used to be regularly fatal, it is now often curable. Treatment may involve surgery, radiation and/or a combination of drugs, most notably cisplatin, which was first used experimentally only a decade ago. Even in severe cases, more than half the patients are cured. When the disease is detected early, the cure rate is nearly 100%.

Regular self-examination, say physicians, is the best way to find the disease early. The exam should be performed after a warm bath or shower, when the scrotal skin is most relaxed. The telltale sign is a lump the size of a pea. Doctors caution that a lump does not necessarily mean cancer, but it should be reported promptly to a physician and checked. ■

A9

APPENDIX C

NEW DIET AID PLAN+PILL
VALENTINE
Caffeine 250 mg.
PPA 37.5 mg.
LOSE 8-25LBS
IN 2-6 WEEKS
100 •$12.50
200 •$17.50
500 •$27.50
VAL
CAFFEIN
250 mg.
PPA
37.5 mg.
OTHER
PRODUCTS
AVAILABLE
SEND
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Not for children, the elderly, pregnant, those taking other drugs, or those with high blood pressure or thyroid conditions. Exceeding recommended dose may cause nervousness, sleeplessness, or change in heart rate or rhythm. As with all diet plans, consult your doctor before taking this product.
ORDER FAST!
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Senator HUMPHREY. Thank you, Mr. Grant. Your observation about selling these elements separately, only to be combined, is very shrewd. Somehow, that had not occurred to me; it should have, I suppose. But that is a very critical observation.

Mr. GRANT. I would like to comment that I am not sure if there are enough good minds in the country to outsmart the number of people in this business. I feel that every time we try to make a move to end something like this, they dream up something else.

Senator HUMPHREY. Yes.

Mr. HOPKINS. Senator?

Senator HUMPHREY. Yes, chief.

Mr. HOPKINS. If you look at some of these drugs that have been passed around here, you will notice that an awful lot of them look like vitamins.

Senator HUMPHREY. Yes.

Mr. HOPKINS. Children pick them up and chew them like they are.

Senator HUMPHREY. Is that right?

Mr. HOPKINS. Yes, sir, they do. They have been brought into Littleton Hospital already.

Senator HUMPHREY. We have asked pretty well all of the questions that can be asked. I think we would be plowing the same ground if we went through. I want to thank each of you for coming long distances and sharing your point of view. I have only one regret, and that is that we did not schedule this panel first.

It is just a natural tendency in Washington, you know, to highlight those with Federal credentials. I think in the future this subcommittee is going to put citizen experts first while the news media is still present, and others, so that your important point of view can be disseminated.

Beyond that, I think it has been a very, very helpful hearing. We had originally postponed this hearing to allow the various Federal agencies to come to some consensus. They have not come to a very useful consensus, if any, and so we are going to move despite that. I thank you again for your efforts today.

At this point, I order printed all statements of those who could not attend and other materials submitted for the record. The record will remain open for 15 days for the submission of additional material, including information specifically requested by the subcommittee during this morning's hearing.

[Additional material supplied for the record follows:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Alcoholism and Drug Abuse
Committee on Labor and Human Resources
United States Senate

RE: S. 497 and S. 503

July 21, 1983

Overview

Look-alike drugs are drug products that contain no controlled substances, but resemble in size, shape and color specific controlled substances with high abuse potential. They may also feature trade markings making them virtually indistinguishable from controlled substances.

Most look-alike drug traffic involves stimulants which typically contain some combination of caffeine, phenylpropanolamine (an appetite suppressant and nasal decongestant) and ephedrine (a nasal decongestant). The most popular look-alike stimulants mimic the drugs Fastin, Ionamin and Biphetamine. Drugs such as Dilaudid and Quaalude are also imitated. The imitation tranquilizers usually contain one or more antihistamines, substances found in cold tablets and sleep aids.

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The look-alike drug industry is a very lucrative business. Dealers reportedly buy pills in quantities of 1,000 or more through the mail and then sell them on the street as controlled substances at a tremendous profit. And since look-alikes are legal, manufacturers can solicit business through mail orders and magazine ads.

S. 497 and S. 503

S. 503, the principal of the two bills, would prohibit the creation, manufacture, distribution or possession with intent to create, manufacture or distribute an "imitation controlled substance." "Imitation controlled substance" is defined as "any pharmaceutical substance other than a controlled substance or prescription drug, or combination of such substances, which is marketed, sold, or distributed to encourage recreational drug use or abuse or any similar nonmedical use" and by representation or appearance would lead a reasonable person to believe that the substance is a controlled substance or purports to act, either alone, in multiple doses, or in combination with a substance or substances, like a controlled substance. The prohibition would not apply to imitation controlled substances used in research or by practitioners as placebos.

Violation would be punishable by a fine of not more than $10,000 or imprisonment for not more than two years or both. The maximum penalties are doubled if a person at least eighteen years of age distributes an "imitation controlled substance" to a person under eighteen.

The bill would also prohibit placing advertisements in newspapers, magazines, handbills or other publications with reasonable knowledge that the purpose of the advertisement is to promote distribution of imitation controlled substances. The prohibition would also apply to posting or

distributing such advertisements in public places. A violation would be punished by a $5,000 fine or imprisonment for not more than one year or both.

Finally, S. 503 would grant federal district courts jurisdiction to restrain drug imitating. Currently, counterfeiting is prohibited, but courts lack the authority to enjoin violations.

S. 497 (a companion bill) would prohibit mailing of "drug abuse oriented advertisements" and shipments of "imitation controlled substances" in response to a "drug abuse oriented advertisement." The U.S. Postal Service would be authorized to dispose of items mailed in violation of this provision. An exemption is provided for imitation controlled substances used as placebos by practitioners or in research.

"Imitation controlled substance" is given the same definition as in S. 503. "Drug abuse oriented advertisement" is defined as any advertisement that encourages, directly or indirectly, the sale, purchase, distribution, use, or abuse of imitation controlled substances for recreational mind alteration or recreational drug experimentation, or nonmedical purposes. An advertisement is presumed to have a medical purpose if it appears in a legitimate medical journal or medical trade publication advertising use of a drug for a medical purpose.

Comments

The non-medical use of look-alike drugs poses numerous risks to the health of persons using them and has been linked to a number of deaths across the country. Both phenylpropranolamine and ephedrine increase the heart rate and raise blood pressure. When taken in a high enough dosage or by an extremely sensitive person, a stroke may result. Antihistamines

are also potentially dangerous. According to AMA Drug Evaluations, the AMA's authoritative clinical guide to drugs, antihistamine "overdosage may be difficult to treat. In children, symptoms resemble atropine poisoning (excitation, convulsions) and, in adults, both depression and stimulation of the central nervous system appear alternately. Cardio-respiratory collapse and death may occur."

Teenagers who use "look alikes" often take them with alcohol, a dangerous combination that may have fatal consequences. An even more insidious danger exists for the person who has been using the imitation drugs in modest amounts and then unknowingly takes the actual controlled substance. If the person experiences mild euphoria after taking three or four look-alike Biphetamines-20's, an equivalent number of Biphetamine-20s will cause intense excitation. Imitation drugs also have the harmful effect of encouraging young people to develop drug abuse habits which could lead to the use of "hard" drugs. Finally, when overdoses of look-alikes occur, physicians and poison control centers are often hampered in prescribing treatment because the identity of the drug taken is unknown.

Because of the significant risks posed by look-alike drugs, the AMA, since December 1981, has supported banning their manufacture, sale and distribution. Pursuant to this policy, the AMA developed model state legislation making it illegal for anyone except those authorized by law to manufacture, process, package, distribute or sell a noncontrolled, nonprescription substance which resembles or is labeled to resemble a specific controlled substance (attached). Some provisions of the AMA bill have been enacted in a number of states. Nonetheless, the AMA

recognizes that because the look-alike drug problem is national in scope and federal agencies lack the authority to combat adequately the problem, federal legislation is needed.

Conclusion

The American Medical Association supports passage of S. 503 and S. 497. The bills provide a comprehensive national response to the look-alike drug problem. They would give federal authorities the necessary tools to deal effectively with the look-alike drug traffic. At the same time, they would not interfere with the legitimate use of imitation controlled substances in research or by a practitioner as a placebo.

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STATEMENT OF THE PROPRIETARY ASSOCIATION

Public Hearing on "Look-Alike" Drugs
Before the United States Senate
Subcommittee on Alcoholism and Drug Abuse
Committee on Labor and Human Resources

July 14, 1983

Preface

The following statement is submitted on behalf of The Proprietary Association, a 102-year old trade association, the active members of which are engaged in the manufacture and distribution of nonprescription or over-the-counter (OTC) medicines. OTC medicines are intended for use by the consumer for the treatment of minor, self-limiting ailments or disorders, such as headache, acid indigestion, cold symptoms, minor skin irritations, and so forth. They include such products as St. Joseph's Aspirin, Vicks Cough Syrup, Noxzema Skin Cream, Tums, and many others. The Association's members are subject to the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301, et. seq.], as enforced by the Food and Drug Administration.

The Importance of Responsible Self-Medication

Nonprescription medicines are the first line of defense in the nation's total health care system. They are used by consumers for the treatment of ailments which are minor and which experience tells us are self-limiting ills which do not require diagnosis and treatment by a physician. The Food and Drug Administration's Commissioner, Arthur Hull Hayes, Jr., M.D., has spoken of the importance of nonprescription medicines:

> "Nonprescription drugs occupy an essential place in health care. The ability of Americans to select, buy and use over-the-counter products to treat conditions that do not require the attention of a doctor is, I believe, a cornerstone of our health care system and of our policy for consumer health protection.
>
> Our job, both industry's and FDA's, is to see that the cornerstone remains firmly in place, and that means that the proprietary drug industry needs to maintain its high standard in the quality, manufacture, and marketing of OTC drugs, and that FDA needs to be both vigilant and efficient in carrying out its responsibilities as the public agency charged with regulating OTC drugs." Statement of Arthur Hull Hayes, Jr., M.D., Commissioner of Food and Drugs, to The Proprietary Association, May 11, 1981.

Responsible self-medication performs valuable and even crucial functions for individuals, the health care system, and the economy. For the individual, it is a familiar, inexpensive and convenient method of treating common discomforts. For the health care system, it provides a shield against a deluge of visits to health professionals for minor, self-limiting disorders. For the national economy, it helps contain the demand for primary care and, in turn, the total cost of formal medical services. As the U.S. Department of Commerce stated:

> "Self-medication with proprietary drugs is a significant factor in the U.S. health care scheme. Escalating costs of health care create a greater need for low cost self-medication than ever before. Seventy-five percent of all illnesses and injuries are initially treated through self-care and OTC medications. If only a small percentage of self-treatment was shifted to medical practitioners, the patient load would disrupt the U.S. health care system." U.S. Industrial Outlook 1978, U.S. Department of Commerce, January, 1978, page 131.

OTC Labeling

Because OTC medicines are designed for use by consumers without medical supervision, federal and state laws and/or regulations require and have for many years required that they contain considerable labeling information for the benefit of consumers. This information includes:

(1) The product name;
(2) a statement of identity;
(3) a list of ingredients;
(4) the net quantity of the contents;
(5) the name and address of the manufacturer, packer or distributor;
(6) the indications for use;
(7) directions and dosage instructions;
(8) warnings and cautionary statements;
(9) drug interaction precautions, if any, and
(10) an expiration date.

The Association is well aware of the critical function which the labeling of an OTC serves in the appropriate and responsible use of OTC medicines. Over the years the Association has made available to consumers through pharmacists thousands of pamphlets titled "Read the Label on Nonprescription Medicines" or, more recently, "Medicine Labels and You." In addition, the Council on Family Health, a non-profit organization funded by many of the Association's members, has sought and obtained millions of dollars worth of public service announcements on radio and television which urge consumers to read the label on OTC medicines.

OTC/Controlled Substance Look-Alikes

The subject of this hearing is the manufacture and distribution of legally formulated OTC medicines so as to make them resemble controlled substances and fraudulently promoting them as such, as well as intentionally misbranding

and promoting OTCs for ingestion in quantities which vastly exceed their recommended dosage. The Association and its members are opposed to such practices because they necessarily involve the marketing of OTCs without adequate labeling or encourage the disregard of OTC labeling as well as encourage the use of OTCs for inappropriate conditions. In the process, they damage the public's confidence in OTCs as the safe and effective medicines which they are if they are used as directed.

The Proprietary Association was first asked to assist in combating the marketing of OTC/controlled substance look-alikes in 1979, when it was invited to and did testify before a legislative committee in Oregon. In 1981, the Association testified in Wisconsin, and since then has organized and keeps updated a compilation of street-drug look-alike legislation which has been considered or enacted in the states (attached as Appendix I). The Association has distributed this material to legislatures, pharmacy boards, pharmaceutical associations, and others in several states, including Colorado, Iowa, Kentucky, Louisiana, Michigan, Nebraska, New York and Washington.

The Association also has discussed the issue with the Drug Enforcement Administration and the American Medical Association both of which have drafted model state bills to prohibit the practice. The Association notes, however, that the practice is illegal under several provisions of existing federal law — specifically the Federal Food, Drug, and Cosmetic Act (see Appendix II). Accordingly, on September 21, 1981, the Association formally requested that FDA take action against the practice (see Appendix III). On September 30, 1981, FDA announced the seizure as street-drug look-alikes of the products of nine manufacturers in five states. The Association also notes that the Post Office Department has obtained a number of injunctions or consent agreements which prohibit persons from receiving street-drug look-alikes through the mails.

Conclusion

Responsible self-medication for minor, transient ills is indeed a cornerstone of our nation's health care system. As FDA Commissioner Hayes has pointed out, however:

> "[S]elf-medication will and should continue to play a very important role in meeting the health needs of most people, but only as long as they can feel sure that the products they select and use will perform as they say they will, that they are manufactured in accordance with high standards and rigorous quality control, and that they can be used with the utmost confidence in their safety." Statement of Arthur Hull Hayes, Jr., M.D., to the Sixth General Assembly of the World Federation of Proprietary Medicine Manufacturers, Ottawa, Canada, October 12, 1981.

The Association strongly echoes Commissioner Hayes' admonition, believing the manufacture and marketing of OTC/controlled substance look-alikes can only damage the public's confidence — a well-founded confidence — that OTC medicines are safe and effective when used for the purposes, in the amounts, and under the conditions described in the labeling.

Sincerely,

THE PROPRIETARY ASSOCIATION

Daniel F. O'Keefe, Jr.
Senior Vice President, General Counsel
and Secretary

Attachments: Appendix I, Controlled Substances/Look-Alike Legislation
Appendix II, The Proprietary Association's Memorandum titled "The Sale of an OTC Drug Outside of Its Original Container Under the Representation That It is A Controlled Substance is Illegal Under the Federal Food, Drug, and Cosmetic Act"
Appendix III, September 21, 1981 letter from The Proprietary Association to FDA Chief Counsel Thomas Scarlett

DOK/ds

7/11/83

LIST OF STATES WHICH BAN STREET DRUG LOOK-ALIKES

(Total - 41)

ALABAMA
ARKANSAS
ARIZONA
CALIFORNIA
COLORADO
CONNECTICUT
DELAWARE
FLORIDA
GEORGIA
IDAHO
ILLINOIS
INDIANA
IOWA
KANSAS
KENTUCKY
LOUISIANA
MARYLAND
MINNESOTA
MISSOURI
MONTANA
NEVADA
NEW HAMPSHIRE
NEW JERSEY
NEW MEXICO
NEW YORK
NORTH CAROLINA
NORTH DAKOTA
OHIO
OKLAHOMA
OREGON
PENNSYLVANIA
RHODE ISLAND
SOUTH CAROLINA
SOUTH DAKOTA
TENNESSEE
UTAH
VERMONT
VIRGINIA
WASHINGTON
WISCONSIN

LIST OF STATES CONSIDERING STREET DRUG LOOK-ALIKES LEGISLATION

ALASKA
HAWAII
ILLINOIS
MASSACHUSETTS
MICHIGAN
NEW JERSEY
OREGON

THE PROPRIETARY ASSOCIATION

The Sale of an OTC Drug Outside of Its Original Container Under the Representation That It Is A Controlled Substance Is Illegal Under the Federal Food, Drug, Cosmetic Act

Introduction

Recently state drug enforcement authorities in several states have informed The Proprietary Association that some unscrupulous individuals in those states purchase OTC medicines which resemble controlled substances, remove them from their original containers, and sell them outside conventional retail channels under the representation they are controlled substances. The question has been asked whether this practice is actionable under federal and/or state law.

Summary

Many states have laws patterned after the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301, et. seq.], which regulates the manufacture packaging, and distribution of drugs in interstate commerce. All states have laws which regulate the practice of pharmacy and the sale of drugs at retail. However, since not all state food, drug, and cosmetic laws are identical to the Federal Act, and not all pharmacy acts are identical (or in many cases even nearly identical) to each other, a brief analysis of the legality of the above-described practice can include a review only of the applicable provisions of the Federal Act. A complete analysis would require a separate examination of each applicable state law. In general, however, it can be said that if the above-described practice is illegal under Federal law, it will be found to be illegal under state law.

The sale of an OTC drug outside of its original container under the representation that it is a controlled substance violates at least two, and in some cases three provisions of the FDC Act, even if interstate commerce is not involved. If interstate commerce is involved, the practice violates from one to three additional provisions. All violations are felonies, subjecting the individual to penalties of imprisonment for up to three years and/or a fine of up to $10,000. The provisions violated by the above-described practice are the following subsections of the Prohibited Acts Section of the Act, Section 301:

(l) Rendering a drug adulterated or misbranded by removing its labeling or otherwise causing it to be adulterated or misbranded:

> Section 301. The following acts and the causing thereof are prohibited:
>
> * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(2) Failing to register as a drug "manufacturer" [defined to include a person who repackages or otherwise changes the container, wrapper, or labeling of any drug package]:

Section 301. The following acts and the causing thereof are prohibited:

* * *

(p) The failure to register in accordance with section 510, the failure to provide any information required by section 510(j) or 510(k), or the failure to provide a notice required by section 510 (j)(2).

(3) Causing a drug to be a counterfeit drug by imprinting on it or its container the trademark, trade name, or other identifying mark of another drug:

Section 301. The following acts and the causing thereof are prohibited:

* * *

(i)(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(4) Adulteration or misbranding of a drug in interstate commerce, or introduction, delivery for introduction, or receipt in interstate commerce of an adulterated or misbranded drug:

Section 301. The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

Discussion

(1) Rendering a drug adulterated or misbranded by removing its labeling or otherwise causing it to be adulterated or misbranded

The FDC Act is to a large extent a pure food and drug law, focusing on the question whether a drug is "adulterated." In general, an individual

who repackages a drug under insanitary conditions or conditions which reduce its quality or strength or which do not comport with "current good manufacturing practice," or who repackages it in an unsuitable container, violates Section 301(k). Section 301(k) prohibits the doing of any act with respect to a drug which results in its being adulterated. Under Section 501, a drug is adulterated:

> (a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health. . . .
>
> * * *
>
> (d) If it is a drug and any substance has been. . . mixed or packed therewith so as to reduce its quality or strength . . . .

Thus, an individual who repackages an OTC drug under insanitary conditions violates Section 501(a)(1). An individual who fails to conform to the detailed requirements of the Food and Drug Administration's "current good manufacturing practice" regulations violates Section 501(a)(2)(B). (The FDA's "current good manufacturing practice" regulations include stringent record keeping, production, and quality control requirements, as well as the requirement that the container of an OTC carry an expiration date for the drug.) If the individual uses an unsuitable container, he violates Section 501(a)(3), and if he mixes an inappropriate substance with the drug, he violates Section 501(d).

The FDC Act is not only a pure food and drug law, however, but also a labeling law, which focuses on the question whether a drug is "misbranded." If a person causes a drug to be inaccurately or incompletely labeled or to be unlabeled altogether, he has similarly violated Section 301(k), which prohibits the doing of any act with respect to a drug which results in its being misbranded. Under Section 502, an OTC drug is misbranded:

> (a) If its labeling is false or misleading in any particular.
>
> (b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count . . . .
>
> * * *
>
> (e)(1) If it is a drug, unless (A) its label bears . . . (i) the established name . . . of the drug, if such there be, and (ii) in case it is fabricated from two or more ingredients, the established name of

each active ingredient, including the quantity, kind, and proportion of any alcohol. . . .

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may dangerous to health, or against unsafe dosage or methods or duration of administration or application . . . .

* * *

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

* * *

(o) If it was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 510, "if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k)....

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packing Act of 1970.

Thus, an individual who sells an OTC drug with no labeling violates Section 502(f). If labeling is present but misleading as to the true identity of drug, he violates Sections 502(a), (e), and (i)(2) and (3). If labeling is present and accurately identifies the drug but fails to identify the name and place of business of the manufacturer, packer, or distributor or the net quantity of the contents, the individual violates Section 502(b).

If the drug is packaged in a container which is made, formed, or filled so as to be misleading, he violates Section 502(i)(1). If the drug is acetaminophen, aspirin, or one of certain iron-containing preparations and is not packaged with a safety closure, as is required by the Poison Prevention Packaging Act of 1970, he violates Section 502(p).

(2) Failing to register as a drug "manufacturer" [defined to include persons who repackage or otherwise change the container, wrapper, or labeling of any drug package]

Section 510 of the Act, passed as the Drug Listing Act of 1972, seeks to ensure that the Food and Drug Administration knows who is performing "manufacturing" operations on drugs. The term "manufacturing" is defined to include:

> "repackaging or otherwise changing the container, wrapper, or labeling of any drug package . . .in furtherance of the distribution of the drug . . .from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. . . ." 21 U.S.C. 360.

The method chosen by Congress to ensure that FDA has such information is to require an annual registration by everyone (except four classes of persons not relevant here) who owns an establishment where such activities are conducted, and an initial submission by that person to FDA, to be revised periodically, listing the drugs "manufactured" by that person, the label and a representative sample of the labeling of such drugs, and other information both mandatory and optional with FDA.

Thus, an individual who performs a repackaging operation, such as removing an OTC drug from its original container and selling it in another container or in no container violates Section 301(p) if he fails to register and update his submissions in the time intervals and with the information required by law or by FDA.

(3) Causing a drug to be a counterfeit drug by imprinting on it or its container the trademark, trade name, or other identifying mark of another.

Section 301(i)(3) prohibits the doing of any act which causes a drug to be a "counterfeit" drug, defined in Section 201(g)(2) as follows:

> (2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

Section 301(i)(3) thus applies in the perhaps limited instances in which the seller, in the above-described situation, identifies the drug or its container as that of a controlled substance by a mark, imprint, logo, etc. on the drug or container itself.

(4) Adulteration or misbranding of a drug in interstate commerce or introduction, delivery for introduction, or receipt in interstate commerce of an adulterated or misbranded drug.

Section 301(a), (b), and (c) prohibit the acts listed above, but only if interstate commerce is involved, that is, only if the drugs cross state lines

in furtherance of the operations or if can reasonably be concluded that the drug has crossed state lines in furtherance of the operation. The operations described to The Proprietary Association of breaking down the original packages of OTC drugs and selling them as controlled substances seem to be of the type which occur wholly intrastate, making Sections 301(a), (b), and (c) of less relevance than the statutes described earlier.

Conclusion

Section 302 of the Act allows the government to seek an injunction against an individual in all of the above-described situations except that of counterfeiting. However, the scienter element involved in the transaction of selling OTC drugs by representing them as controlled substances brings into play the more likely sanction, covered under Section 303(b) of the Act which subject inviduals who violate any provision of Section 301 "with the intent to defraud or mislead" to penalties of up to three years in prison and/or $10,000 in fines. Finally, Section 304(a) subject the violative drugs to seizure.

In view of the pervasive nature of the adulteration and misbranding provisions of the FDC Act, it would appear that the sale of an OTC drug outside of its original container under the representation that it is a controlled substance is actionable by Federal agents under the FDC Act and by state agents under any state acts with similar provisions.

- o0o -

GMF/sbm
5/22/81

The Proprietary Association
1700 PENNSYLVANIA AVENUE, N.W. / WASHINGTON, D. C. 20006 / PHONE (202) 393-1700

September 21, 1981

Thomas Scarlett, Esq.
Chief Counsel
Food and Drug Administration
Department of Health and Human Sciences
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Scarlett:

There is evidence of an apparently growing practice in many areas of the country of the manufacture and/or distribution of tablets and capsules in such a way as to make them look like, and convince purchasers that they are, controlled substances. We are informed that, typically, these counterfeit look-alikes are manufactured to resemble controlled substances by imitating the capsule size, colors and markings of the legitimate controlled substances, that they are typically sold in large quantities (e.g., bottles of 1,000), and that they are later distributed in small quantities — without labeling — in schools, truck stops, and on street corners. Although these tablets and capsules often consist of acceptable OTC ingredients and/or combinations at legal dosage levels, they are not properly labeled — at least when sold to the ultimate consumer — as OTC medicines in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act.

As the 100-year-old trade association which represents manufacturers and distributors of non-prescription or over-the-counter medicines, this Association strongly objects to the practice outlined above. We emphasize that our members do not engage in this practice which appears not only to be illegal under existing law, but also constitutes a threat to health, and damages the public's perception of OTC medicines as safe and effective when used according to label directions. We strongly urge the FDA to investigate this practice and take action under the anti-counterfeiting and/or misbranding provisions of the Federal Food, Drug, and Cosmetic Act. (21 U.S.C §§321(g)(2), 331(i), and 352(i)).

As you know, an OTC medicine under the Federal Food, Drug, and Cosmetic Act is one which can be used safely and effectively by the consumer on the basis of its label directions, without the supervision of a physician. Because of the critically important function which the labeling of an OTC serves, the FDC Act and/or FDA regulations require that it include:

(1) the product name,
(2) a statement of identity,
(3) a list of the active ingredients,

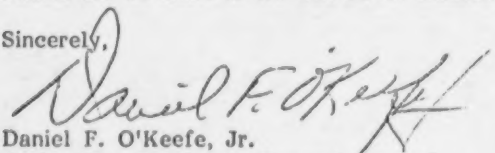
(4) the net quantity of the contents,
(5) the name and address of the manufacturer, packer or distributor,
(6) the indications for use,
(7) directions and dosage instructions,
(8) warnings and cautionary statements,
(9) drug interaction precautions, if any, and
(10) an expiration date.

The Association appreciates the importance of labeling of an OTC. Over the years it has made available to consumers through pharmacists thousands of pamphlets titled "Read the Label on Nonprescription Medicines" or, more recently, "Medicine Labels and You." In addition, the Council on Family Health, a non-profit organization funded by many of the Association's members has sought and obtained millions of dollars worth of public service announcements on radio and television which urge consumers to read the label on OTC medicines.

The Association favors and has always favored only the appropriate use of OTC medicines; that is, their proper use in accordance with label directions. We view the practice described in this letter as harmful to the public interest. At a minimum it reduces public confidence in safe, effective, and properly labeled OTC medicines and, therefore, in appropriate self-medication.

Please let us know if we can be of assistance in this matter.

Sincerely,



Daniel F. O'Keefe, Jr.
Senior Vice President, General Counsel
and Secretary

DOK:bws

BODY DYNAMICS INC.
ADVERTISING AND MODELING AGENCIES
HEALTH CARE PRODUCTS
VITAMINS, STIMULANTS & DIET AIDS
P.O. Box 11083 Indpls., IN 46201
1-317-631-6718
WE SHIP U.S. MAIL-UPS-AIR FREIGHT-C.O.D.

August 17, 1983

Nancy Wolicki
Council Alcohol Drug Abuse/Sub-Committee
U. S. Senate
Room 428 Dirksen Building
Washington, DC 20510

Dear Ms. Wolicki:

In regards to Senate Bills S.497 and S.503, this testimony is for the record.

I feel these bills are highly discriminating and unconstitutional because these bills clearly are for the soul purpose of putting small businesses out of business in favor of large businesses. Our products are being called look-alikes and now act-a-likes. Our company sells no products that resemble any controlled substance on the market today.

I feel we are being discriminated against because we are in competition with big drug companies, such as Thompson Medical Co., Inc., due to the fact that they feel we are hurting their sales, which actually they are the true manufacturer's of look-alikes.

Enclosed is a copy of our consent agreement with the United States Postal Service, stating in Section (2) what we cannot sell of these shapes and colored products with our logo's.

Yet, upon going in any Grocery or Drug Store, you will find these products for sale to anyone, no age limit. Our 8 year old purchased these products with no problem or questions asked.

Our products are sold only to 18 year olds and older, we take Birthdates on all orders, our average age customer is 29. We have over 150,000 people participate in our diet program on a regular basis.

I feel the main abusers are Thompson Medical, who sell Dexatrim containing 200 mg Caff, 75 mg PPA, which is an exact copy of Smith, Kline and French Dexedrine, Caffedrine, sold as a safe and effective stimulant which is a Green/Clear, that we are not allowed to sell, Dex-a-diet which is another Green/Clear with 200 mg Caff, 75 mg PPA, PVM - Brown/Clear, which used to resemble a drug and yet we are not allowed to sell it, and Resolution I - Blue/Clear which is a copy of Beecham Lab's Fastin.

(Con't)

Plus many more which we have enclosed for your investigation. For your convenience we are sending the 1981 Edition of (PDR) Physicians' Desk Reference with the places marked which we have mentioned on the previous page.

Dexatrim is advertised as "Now Available at prescription strength without a prescription", this is false advertisement, since the product is not prescription strength. Also, most cough formulas contain Dextromethorphan, advertised as "Effective as Codeine, but non-narcotic", this is an act-a-like claim. Another well known product is Coca-Cola which advertises "Coke is the Real Thing, never lets you down". Coca-Cola put Cocaine in Coke, but was outlawed at the turn of the Century, replacing it with Caffein, however, they still use an extract from the Coca Leaf, but will not reveal the formula to anyone. This product is a stimulant cola sold everywhere to everyone including Schools, with 60 to 80 mg Caff and no Caffein Warnings. One Coke and one chocolate candy bar will give you the equivilant of between 200 to 300 mg of Caffein. Brewed Coffee has not caffein warnings and there are 150 mg Caff. per cup, many people who drink 10 cups of coffee per day will obtain over 1500 mg. of Caffein.

Childrens cough formulas contain PPA and alcohol in much higher levels than our products. I consider these cough medicines as cheap bottles of wine which the children purchase to get drunk on.

How about Miller Beer advertisements? (picture enclosed) "Miller High Life", they are essence saying that you can get high on Miller Beer. I could go on forever with examples such as these, however the point I am trying to get across is that no Government Agencies will challenge these large Company's claims.

Since all look-a-like drugs which were produced in the past were printed with counterfeit Logo's on these large companies empty capsules and selling them to everyone until it became unpopular and then they stopped selling the empty capsules, no government agency challenged them, yet our manufacturers were raided by FDA officials and United States Marshalls, seizing products, printing machines and printing plate rollers. When asked what they were going to do about the Big Companies they flat told us "We will not take them on, but we will take you on", this is discrimination at the highest level.

As far as people dying and over dosing on Caffein products, this is total nonsense. Our company keeps in close contact with the FDA Poison Control Center and Mr. Lee Drakin has informed me personally that he had only (8) calls on Hospital cases for caffein overdose in the last year (1982) none of which turned out to be serious.

The real killer of children and adults is Alcohol (Get High on Miller Beer) for every case of a narcotics death there are over 1,000 caused by alcohol in auto accidents alone. These are the real killers, yet no one is trying to stop the selling of Alcoholic Beverages.

(Con't)

Our company has complied, to the letter, with the postal agreement on products that we cannot sell. We know that there are still many people selling exact look-alike products in the Industry and they are still operating. Enclosed is a flyer from a company in Florida which is still selling triple combinations and exact look-a-likes. I feel action should be taken against this individual and a few more who are making it bad for the rest of us.

We offer our cooperation in any way to rid the industry of these abusers, I would also like a difinition of what is a look-a-like and an act-a-like, we have written to the FDA on many occasions asking for a ruling on this subject and have yet to get a response from them.

I hope I have given you enough information and insight as to what our industry is up against. I wish to work within the boundries of your laws, but have to know those laws and specifically how they are going to be interpreted. I am prepared to go into federal court to ask for an interpretation of any of these proposed legislations, if and when passed.

Yours truly,

Richard A. Deer
President/Owner

Encl:

RAD/bh

SCM:ph
G.C. 270-81-P

UNITED STATES POSTAL SERVICE

WASHINGTON, D. C. 20260-1100

In the Matter of the Complaint Against	)	
	)	
HEALTH RESEARCH	)	
P. O. Box 11063	)	P.S. Docket No. 12/38
	)	
at	)	
	)	
Indianapolis, Indiana 46201	)	

CONSENT AGREEMENT

In consideration of Complainant's agreement to seek the indefinite suspension of proceedings before the United States Postal Service in P.S. Docket 12/38, Respondent, Richard Deer, owner of Health Research, agrees to the following terms and conditions.

1. This Agreement relates exclusively to the pending proceedings brought under 39 U.S.C. § 3005, and shall not constitute a defense or release of the Respondent of any responsibility for violation of any other statute. This agreement is for settlement purposes only and does not constitute an admission by the Respondent of a violation of 39 U.S.C. § 3005.

2. Respondent agrees to cease and desist immediately from advertising, offering for sale, selling, or otherwise furnishing the following drug products:

(a) All hard gelatin solid black or yellow capsules.

(b) All round white double-scored tablets, known and advertised variously as mini-whites or mini-white crosses.

(c) All round white or orange colored tablets imprinted with "BT 72" or any combination of letters and numbers which reasonably could be mistaken by another for the product Preludin produced by Boehringer-Ingelheim Ltd.

(d) All blue or white oblong tablets containing blue or green specks which could reasonably be mistaken by another for one or more Lemmon Company products, including Adipex-P, Obestat, Adiloss, and for a form of methamphetamine produced by Danbury Pharmaceuticals.

(e) All round white tablets marked "714," with or without the words or any variant thereof "Lemmon" or "Rorer" which could reasonably be mistaken by another for the Quaalude product of Lemmon Company (formerly of Rorer Co.).

(f) All triangle or shield-shaped tablets colored green, gold or pink, whether plain or imprinted with any letter(s) or number(s).

(g) All hard gelatin capsules described as green and clear, blue and clear, white or cream and clear or brown clear which could be mistaken by another for, respectively, the dexamyl product of Smith, Kline & French, the Fastin product of Beecham, Inc., the Eskatrol and Dexedrine products of Smith, Kline & French.

(h) All pink oval tablets sometimes advertised as "pink footballs" that could reasonably be mistaken for amphetamines such as the Phillips-Roxanne product and all pink heart-shaped tablets.

(i) Respondent agrees to cease and desist beginning 60 days after the execution of this agreement the advertising, sale or furnishing of drug products marked "MOLE" or "MOLIE" or any reasonable variant of that name.

3. None of Respondent's advertising, promotional or other material made available to members of the public in connection with the sale or dispensing or offering for such sale or dispensing of any paragraph 2 products shall contain any drawing, photograph or other graphic representation nor any oral description of the appearance of the product or products involved. It shall not be a violation of this Agreement to designate such products as tablets or capsules, to identify their contents, or to identify and distinguish among dosage forms as necessary.

4. All written or printed advertising material, labeling, and other material made available to members of the public in connection with the sale or dispensing of any drug product containing phenylpropanolamine shall contain the following legible warning (in these or similar terms):

> Not for children, elderly, pregnant, those taking other drugs, or those with high blood pressure or thyroid conditions.

5. All written or printed advertising material, labeling, and other material made available to members of the public in connection with the sale or dispensing of any drug product containing caffeine or ephedrine shall contain the following legible warning (in these or similar terms):

> Exceeding recommended dose may cause nervousness, sleeplessness or change in heart rate and rhythm.

PRODUCT SELECTION GUIDE

Diet Aids • Sleep Aids

Diet Aids

30 **DEX L10 Green Triangle**
Caffeine 100 mg
Phenylpropanolamine HCL 33.3 mg

31 **DEX L10 Orange Triangle**
Caffeine 100mg
Phenylpropanolamine HCL 33.3mg

32 **DEX L10 Pink Triangle**
Caffeine 100mg
Phenylpropanolamine HCL 33.3mg

Sleep Aids

33 **Blue #10 Sleep Aid**
Pyrilamine Maleate 25mg

34 **Dele 156**
Pyrilamine Maleate 25mg

35 **714 Sleep Aid**
Pyrilamine Maleate 25mg

36 **Pink Capsule Sleep Aid**
Pyrilamine Maleate 25mg

37 **Blue & Red F-66**
Salicyamide 100mg
Salicyamide 100mg
Acetaminophen 100mg
Doxylamine Succinate 7.5mg
Prophenpyridamine Maleate 7.5mg

38 **Yellow 122 Sleep Aid**
Salicylamide 150mg
Acetaminophen 250mg
Doxylamine Succinate 7.5mg
Prophenpyridamine Maleate 7.5mg

39
F-66
Salicyamide 100mg
Acetaminophen 100mg
Doxylamine Succinate 7.5mg
Prophenpyridamine Maleate 7.5mg

40 **LEMON 714 Sleep Aid**
Salicylamide 50mg
Acetaminophen 250mg
Doxylamine Succinate 12.5mg

41
Ceftual II
Salicylamide 150mg
Acetaminophen 250mg
Doxylamine Succinate 25mg

42
II Sleep Aid
Salicylamide 150mg
Acetaminophen 250mg
Doxylamine Succinate 25mg

43
LENNON 714 Sleep Aid
Salicylamide 50mg
Acetaminophen 250mg
Doxylamine Succinate

BROCHURES AVAILABLE IN QUANTITY -- PRICES ON REQUEST

Our Terms...

- ☐ We Accept ONLY Cash and Money Orders.
- ☐ No personal checks accepted.
- ☐ Please send all cash by CERTIFIED MAIL.
- ☐ Consult our current Price List & Order Form for product prices.
- ☐ All orders must be made on our Price List & Order Form
- ☐ Money sent by Western Union MUST be pre-arranged.
- ☐ Company checks will delay shipment until checks have cleared.

PRODUCT SELECTION GUIDE

Decongestants

1
335
Caffeine 150mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

2
DEX
Caffeine 200mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

3
Yellow RUS
Caffeine 100 mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

4
Green & Clear
Caffeine 150mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

5
RJR
Caffeine 200mg
Phenylpropanolamine HCL 35m
Ephedrine Sulfate 25mg

6
Blue & Clear
Caffeine 150mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

7
Black RUS
Caffeine 100mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

8
White with Green Specks With Line
Caffeine 200 mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

9
Mini White Cross
Ephedrine Sulfate 25mg

10
Black 127
Caffeine 200mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

11
White Bar/Blue Specks
Caffeine 150mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

12
Pink Footballs
Caffeine 150mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

13
Blue Bar/Blue Specks
Caffeine 150mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

14
Pink Hearts
Ephedrine Sulfate 25mg

15
ST 72
Caffeine 175
Phenylpropanolamine HCL 37.5 mg
Ephedrine Sulfate 25mg

16
3 Way Pink Hearts
Caffeine 175mg
Phenylpropanolamine HCL 37.5 mg
Ephedrine Sulfate 25mg

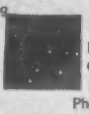
17
Double C's
Ephedrine Sulfate 25mg

18
Green Round
Ephedrine Sulfate 25mg

19
Mini White Cross 3 Way
Caffeine 25mg
Phenylpropanolamine HCL 10 mg
Ephedrine Sulfate 25mg

20
Merrell 175
Caffeine 175mg
Ephedrine Sulfate 25mg
Phenylpropanolamine HCL 50mg

21
10-845
Caffeine 140mg
Ephedrine Sulfate 25mg
Phenylpropanolamine HCl. 37.5 mg



22
M L E
Caffeine 325mg
Pseudoephedrine Sulfate 30mg
Phenylpropanolamine HCL 25mg

23
White With Blue Specks
Caffeine 175mg
Ephedrine Sulfate 25mg
Phenylpropanolamine HCL 37.5mg

24
Brown & Clear
Caffeine 100mg
Ephedrine Sulfate 25mg

25
10-954
Caffeine 140mg
Ephedrine Sulfate 25mg
Phenylpropanolamine HCL 37.5mg

26
White & Clear
Caffeine 150mg
Phenylpropanolamine HCL 35mg
Ephedrine Sulfate 25mg

27
20/20 White With Red and Blue Specks
Caffeine 250mg
Ephedrine Sulfate 25mg
Phenylpropanolamine HCL 35mg

28
Black P-175
Caffeine 75mg
Ephedrine Sulfate 25mg
Phenylpropanolamine HCL 37.5mg

29
Decon-25 Tablet
Thick White Cross
Caffeine 25mg
Phenylpropanolamine HCL 10mg
Ephedrine Sulfate 25mg

DEEP SOUTH

369 EAST 900 SOUTH, SALT LAKE CITY, UTAH 84111

Dear Customer:

We have purchased the remaining inventory and assets of Inter-Bay Distributing Co., Deep South Distributing Co. and Deep South Pharmaceutical Co., for liquidation.

Enclosed are brochures and price lists for the remaining inventory. All orders will be processed on a first come, first served basis. (Please indicate 1st & 2nd choices).

The following procedure must be followed to obtain the **last** of the 3-way formula pills:

1. Send bank money order (not postal money order) payable to: Deep South, 369 East 900 South, Salt Lake City, Utah 84111.

Once again I must remind you that we have only a limited supply of product to liquidate, and **60 days** to do so. This will be your last chance to purchase these products forever, so don't delay, place your order now.

If you would like to stay on our mailing list, please write and tell us so, otherwise your name will be deleted from the list.

(Please Type or Print Plainly)

Name : _____

ADDRESS _____

CITY _____

STATE _____ ZIP _____

PHONE NUMBER (____) _____

P.S. Coming soon: A complete line of two-way stimulant capsules and tablets.

PRICE LIST AND ORDER FORM

Refer to our Product Selection guide for product descriptions.

No.	Quantity	Amount
1		$75.00
2		$75.00
3		$75.00
4		$50.00
5		$75.00
6		$50.00
7		$75.00
8		$50.00
9		REFER TO CHART A
10		$75.00
11		$35.00
12		$50.00
13		$35.00
14		REFER TO CHART A
15	SOLD OUT	SOLD OUT
16		$60.00
17		REFER TO CHART A
18		REFER TO CHART A
19		REFER TO CHART A
20		$60.00
21	18-789	$100.00
22		$100.00
23		$50.00
24	SOLD OUT	SOLD OUT
25		$75.00
26		$50.00
27		$100.00
28	SOLD OUT	SOLD OUT
29		REFER TO CHART A
30		REFER TO CHART A
31		REFER TO CHART A
32		REFER TO CHART A
33		REFER TO CHART A
34		REFER TO CHART A
35		REFER TO CHART A
36		REFER TO CHART A
37		REFER TO CHART A
38		REFER TO CHART A
39		REFER TO CHART A
40		$40.00
41		$40.00
42		$40.00
43		$40.00
	Total	

Quantity Prices

CHART A

Quantity	Cost	Per	Total
1,000	$50.00	1000	$ 50.00
5,000	$35.00	1000	$ 175.00
10,000	$30.00	1000	$ 300.00
50,000	$25.00	1000	$1250.00
100,000	$18.00	1000	$1800.00

4, 6, 8, 12, 23, 26

Quantity	Cost	Per	Total
1000	$50.00	1000	$ 50.00
10,000	$40.00	1000	$400.00

21, 22 & 27

Quantity	Cost	Per	Total
1000	$100.00	1000	$ 100.00
10,000	$ 85.00	1000	$ 850.00
20,000	$ 75.00	1000	$1500.00
50,000	$ 50.00	1000	$2500.00

40-43

Quantity	Cost	Per	Total
1000	$40.00	1000	$ 40.00
5000	$30.00	1000	$150.00

DEEP SOUTH
369 EAST 900 SOUTH
SALT LAKE CITY, UTAH 84111

(Please Type or Print Plainly)

SHIP TO: _____
(Name of Company)

ADDRESS: _____

CITY: _____

STATE: _____ ZIP: _____

PHONE NUMBER (___) _____

Please provide phone number so that we can notify you immediately if we are out of stock of an item.

Your GUARANTEE of QUALITY

This certificate is your guarantee that the product labelled **FLORIDA ROCK** is the best quality on the market. If this product is damaged, spoiled or discolored due to processing or packaging, return it to us and we will provide a replacement at absolutely no cost to you.

FLORIDA ROCK!

Get on top of the ROCK!

We've got it.
And you can get it today

FLORIDA ROCK INCENS

the ultimate high!

QUANTITY	PRICE LIST	PRICE
1 gram		$40.00
1 ounce		$550.00
1/4 pound		$900.00
1/2 pound		$1,600.00
1 pound		$3,000.00
1 kilo		$4;000.00
2 kilo		$3,500.00 each

Marketing Information

A crystal-like, pure white rock FLORIDA ROCK is a truly unique insense that has been especially created for long-lasting pleasure. ... and is the BEST buy in town.

Our Terms ...

- ☐ We Accept ONLY Cash and Money Orders.
- ☐ Consult our current Price List & Order Form for product prices.
- ☐ No personal checks accepted.
- ☐ Please send all cash by CERTIFIED MAIL.
- ☐ Money sent by Western Union MUST be pre-arranged.
- ☐ Company checks will delay shipment until checks have cleared.
- ☐ ALL orders must be made on our Price List & Order Form.

Retailer and distributor inquiries welcome contact us for our complete line

Distributed By

Senator HUMPHREY. The hearing is now concluded.
[Whereupon, at 1:01 p.m., the subcommittee was adjourned.]

○